TenU



Guide 2023



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Research England

Preface

University technology transfer offices (TTOs) and venture capital firms (VCs) share a common goal: work with inventors, founders and entrepreneurs to take innovative technologies to market, in order to increase societal impact and generate economic growth.

But shared aspiration doesn't make building successful companies easy. Commercialising early-stage science and deep tech is difficult. It is particularly daunting to take a non-validated technology with no customers, no revenue and potentially no market, and turn it into a high growth business.

Company formation and growth involves many stakeholders that should all benefit from the process – inventors, founders, key employees, universities, investors, and research funders. All these parties have a critical role to play. But two entities have particular power to positively shape the founders' drive: the TTOs who provide the technology licence and the investors who provide the capital.

However, negotiations between TTOs and VCs can be complex. The negotiations may be costly in terms of person-hours, legal bills, and sometimes bruised egos. A successful outcome requires all parties to work together and align on a common proposition.

The USIT Guide was created to facilitate faster negotiations, to identify a landing zone for what a positive deal should look like and to demonstrate that there is a shared commitment across both the TTO and VC communities to work together to build businesses that can change the world. This guide consolidates the many hard lessons learnt from years of negotiating major and complex spin-out deals. The parties involved have helped found over 300 spin-outs in the last five years. It offers a quick reference on best practice for structuring contested items, such as equity, royalties, and milestones, as well as distinct positions around sub-licensing, knowhow, royalties, and due diligence. It draws on decades of experience from organisations that have completed hundreds of these deals across numerous industries—and makes the benefit of their experience available for all.

Under the stewardship of TenU, the USIT Guide was developed throughout 2022 and agreed upon by experienced representatives of leading TTOs and VCs (listed below). The document benefitted from detailed comments by specialised law firms Goodwin Procter and Taylor Wessing and a sector-wide consultation process including the BioIndustry Association (BIA), the British Private Equity and Venture Capital Association (BVCA) and PraxisAuril.

The Guide is life sciences focussed but the principles and insights apply to all sectors. In some instances, where recommendations are sector-specific, this is clearly laid out.

We invite all involved in creating university spinouts to embrace the goodwill inherent in the USIT Guide. Use it to facilitate the technology transfer process, accelerate deals, strengthen investor returns and secure a sustainable research base. Use it to build enduring companies that increase societal impact and generate healthy economic growth. Use it to succeed.



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Endorsements

"The USIT Guide has come out of the deep professionalism and commitment of UK tech transfer offices to collaboration: sharing approaches internationally, and working with others - particularly investors - to make our ecosystem more effective. TenU has taken a lead, but this is supported by the wider international links of the US, UK and European tech transfer communities. I believe the Guide will help demystify the process for the less experienced. I also believe it will speed up spin-out development, maturity and scale-up, enriching our ecosystem and generating more technology for wider societal benefit. **Research England wholeheartedly** commends the Guide for consideration by the university sector and its partners"



Professor Dame Jessica Corner FMedSci MAE RN Executive Chair Research England "Exploring current practice in order to build best practice is highly beneficial to the sector. That this initiative has brought together the university and venture capital community with a shared purpose is particularly encouraging."



Alison Campbell OBE PhD Chief Executive Officer Government Office for Technology Transfer

"Strengthening the connection between venture capitalists and universities is key to unlocking innovation and growth. This report provides a practical guide for policymakers that will accelerate the formation of innovative and dynamic spin-out companies."



Professor Geraint Rees Vice Provost (Research, Innovation and Global Engagement) UCL

"PraxisAuril welcomes the USIT Guide as a positive and proactive step to improving the environment for research commercialisation in the UK. TenU's UK members are part of our KE professional community, which puts professional development and peer-to-peer learning at the heart of our support to advance research commercialisation right across the university sector."



David Russell Chief Executive Officer PraxisAuril "The BVCA is proud to have supported TenU in the production of the USIT Guide. This will help bridge the gap between founders, universities and investors so that spinouts can be created quickly and be in the best position to start their funding journey. Creating the right funding ecosystem for spin-outs will help build on the fantastic ideas coming from universities in all the nations and regions of the UK."



Michael Moore Chief Executive British Provate Equity and Venture Capital Association, BVCA "Having a guide written by experts and participants on all sides helps everyone to answer the question 'Is this deal within normal boundaries?' without fixing defined terms which may not suit any individual deal. Here's to speeding up dealmaking!"



Steve Bates OBE FMEdSci Chief Executive Officer BioIndustry Association

"The USIT Guide is an amazing initiative that builds on the US recommendations, but customized for the specific needs of UK stakeholders. This should be a hugely helpful resource for VCs, entrepreneurs, and universities. Hopefully this will add speed and transparency to negotiations and secure win-win outcomes. Bravo!"



Orin Herskowitz SVP of Applied Innovation and Industry Partnerships Columbia University "The USIT Guide provides information and context, gives some strategies and hints on how to approach university licensing, and offers consistency in approach for university communities. These preparatory steps are essential, regardless of the technology area, university or VC at the table. The end result will be a more streamlined process to start-up launch and a greater likelihood of agreements that are fit for purpose."



Lesley Millar-Nicholson Executive Director MIT Technology Licensing Office

"Founding a spin-out is challenging even for the most entrepreneurial researchers, who find a maze of terms and conditions to be negotiated, often before the full potential of their company's prospects is understood. Each deal has its specific requirements but there are also many commonalities. The USIT guide distils the experience of leading technology transfer practitioners and experienced investors to provide an invaluable reference for all parties. It will accelerate this vital sector and thus support the economic transformation that innovation will bring."



Professor Luke Georghiou Deputy President and Deputy Vice-Chancellor University of Manchester



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Executive Summary

The University Spin-out Investment Terms Guide (the USIT Guide) was developed to offer consistent and transparent recommendations, to minimise transaction costs and to simplify complex negotiations. With a focus on life sciences, the Guide provides common negotiation approaches that can apply to the majority of sectors, helping to accelerate deals and strengthen the ability of university entrepreneurs to create transformational businesses.

By coming together to develop the Guide, the contributors demonstrate a common desire to build self-perpetuating ecosystems, with strong relationships between investors, universities and founders. Relationships made of shared positive experiences, as well as of an improved understanding of each other's challenges and constraints. Relationships made stronger through synergistic, two-way arrangements such as continued laboratory access, broadened access to networks, and increased growth capital for spinouts at every stage. Strengthened relationships, in turn, will support the next generation of spin-outs, helping them to achieve viability more quickly, spur economic growth and create jobs, whilst solving the biggest societal challenges.

The USIT Guide is structured in four sections. It provides common negotiation approaches and articulates distinct positions in a way that is easily accessible, fair and without bias to any party.

The first section introduces the reader to university spin-out investment and shares the vision for the Guide.

The second section provides case studies of how these terms have played out in practice. One set of case studies provides detailed and rare insight into real-world deals, anonymised to protect confidential information. A second set of case studies provides company stories from foundation to exit, illustrating their societal impact and contribution to job creation and economic growth. The third section contains detailed recommendations, in two parts, for negotiating deal terms between universities and investors. The first part focuses on term sheets for spin-out formation; the second part on heads of terms for licence agreements. Each term is given detailed consideration, providing clear recommendations on common practice and explaining the rationale for different positions under different scenarios.

The fourth section offers a glossary of terms to help familiarise readers with the language of investment deals.

Looking to the future, we expect the USIT Guide to be updated from time to time to reflect the changing landscape of university ecosystems, the availability of capital and the evolution of best practice.

Recommendations

The Guide is intended to be used as a reference point and to be used sensibly by practitioners who must adapt to and recognise the specifics of each deal. The Guide makes the following recommendations.

- Landing zone: The USIT Guide is structured to create a 'landing zone' of terms, so that conversations can be guided rapidly to a place where agreement can be reached more quickly. That said, all deals must be understood and negotiated in their entirety, and with goodwill and compromise from all parties. It is important that users of the Guide do not cherry-pick approaches to specific elements of a deal.
- Impact-first approach: A factor that influences the perceived success of spin-outs is the university innovation policy. It is our clear recommendation that the university should take an impact-first approach and strive to

deliver technology-benefit to society. We recommend that the university should not seek to maximise each deal but to strive for optimal deals that represent good market value and can enable a greater entrepreneurship culture across the university.

- Back-weighted deals: All parties should be focused on ensuring the licensing and royalty terms are structured to help the spin-out company to preserve early cashflow and to spend investment on progressing the technology development.
- Equity position: We recommend that the pre-investment equity 'landing zone' position for a university who is supporting a spin-out company with a licence of a foundational piece of technology be between 10-25% of the company. The levers which help to tune the exact final location of the equity proposition are described in full in Section 3.2.1 (Leveraging Equity).
- Royalty windows: There are many factors to be considered in relation to licensing, including upfront payments, annual fees, development milestones, sales milestones, and royalty rates. These need to be considered in conjunction with the equity element and are described in Section 3.3.1 (Royalties and Success-Based Milestones). For guidance, it is recommended that in know-how only or very early-stage technologies a typical royalty window be between 0.5% and 2% and in technologies that are more progressed a typical royalty window be between 2% and 5%. In advanced technologies the royalty window may exceed 5%.
- Multi-factor process: The Guide recognises and acknowledges that creating spin-outs is a complex process and that many factors must be considered. These include the protection strategy for early-stage intellectual property, the recognition of the contributions of inventors and the company founding team, long-term access to lab and research infrastructure, the nature of the licence to the company, the investment strategy deployed, the formation of the right board and advisory team, access to on-going university technology development, and a host of other factors that can enable or hinder a company's development. It is critical that we do not reduce the challenges to a single factor, and recognise the complexity of creating spin-outs.

We encourage stakeholders to work collectively to deliver faster and more effective spin-out development. This will ultimately increase economic growth and job creation, and provide more solutions to societal challenges through the development and application of transformative technologies from university research.



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Introduction

1.1 What is the USIT Guide?

The University Spin-out Investment Terms Guide (the USIT Guide) is a set of best-practice investment and licensing terms for spinout company formation. The guide has been developed and agreed upon by leading global VC investors and universities.

The Guide has been designed to create a landing zone for a fair deal and to share best practise in a transparent manner for all stakeholders in order to speed up the process to form university spin-outs. The aim is to enable investors to make financial returns and universities to deliver positive impact from their research.

11.1 Why is it needed?

The USIT Guide accelerates and scales up the commercialisation of university research by providing university executives, faculty members, inventors, spin-out founders and investors a reasonable, mutually understandable starting point for contractual negotiations.

The Guide builds familiarity with the operating environment, providing clarity on what is fair and normal in spin-out investments. It helps to demystify each term, explaining the various constraints and success factors required to make it work in a contract.

Many can benefit from this guidance. Firsttime investors or spin-out founders will find it a valuable point of reference when doing deals. Universities and institutional investors will find it helpful as a basis for setting their technology commercialisation policy.

Our goal is to help to create more impactful companies, more quickly. This guide is a tool to support this ambition.

1.1.2 What does success look like?

The USIT Guide's goal is to spur economic growth, create jobs and support the creation of university spin-outs that can commercialise transformative technologies to solve big societal challenges. As a result of this guidance, we aspire in five years' time to see a significantly stronger portfolio of spin-outs generated from UK university research. We want to strengthen the portfolio at every stage of the journey, from pre-seed and seed through to series A and B, growth capital, IPO or trade sale. We wish to see today's nascent laboratory ideas, spun out into commercial businesses, generating revenue as high value products and services that continue to grow and evolve to ultimately become national and international leaders competing successfully in a global arena.

We also wish to build a self-perpetuating ecosystem, with strong relationships between investors, universities and founders. An enhanced ecosystem will be built on an improved understanding of each other's challenges and constraints and also on shared positive experiences.

Relationships will be strengthened through synergistic, two-way arrangements such as continued laboratory access and support for spinouts or support from universities for developing further grants.

If managed successfully, the ecosystem will be built on a virtuous circle in which individuals and successful entities give back through mentorship, support, philanthropy, and R&D investment. This, in turn, will support the next generation of spin-outs and help them to achieve viability more quickly, avoiding some of the contractual and operational pitfalls that have caused many promising spinouts to fail.

1.2 How was the USIT Guide created?

The concept of the USIT Guide was derived at a TenU meeting. TenU is an international collaboration, formed to capture effective practices in research commercialisation, and share these with governments and higher education communities. Its members work together to increase the societal impact of research. TenU is made up of the technology transfer offices of the University of Cambridge, Columbia University, University of Edinburgh, Imperial College London, KU Leuven, University of Manchester, MIT, University of Oxford, Stanford University, and UCL.

In 2022, TenU's six UK members convened a group of venture capital investors, seasoned in investment in university spin-outs in the UK, to hold a series of workshops. As the six most research-intensive universities in the UK they have registered 376 new companies in the last five years and, over the same period, have raised over £8.6 billion in investment for their active spin-outs.

The investors include the funds associated with universities, Oxford Science Enterprises and Cambridge Innovation Capital, and the independent VC firms Abingworth, Advent Life Sciences, Amadeus Capital Partners, Octopus Ventures, and Sofinnova Partners.

The universities and investors agreed a set of recommendations across 22 inter-related items that define a typical university spin-out investment deal. The items include terms defining the distribution of economic return (such as equity stakes and licensing royalties), alongside terms to ensure the operational freedom of the spin-out, the university and the investor (like warranties, liabilities and reservation of rights). Although modelled using the life sciences sector, the USIT Guide recommendations are transferable to multiple sectors. This work was welcomed and referenced by the UK Government in the July 2022 UK Digital Strategy policy paper. The USIT Guide builds on the example of TenU member Orin Herskowitz of Columbia University, who convened a series of roundtable meetings with US universities and life science investors to create a common term sheet designed to accelerate US university spinout licensing deals. TenU, in line with its goal of learning from international best practice, decided to test this approach in the UK. The US recommendations provide an excellent exemplar, though it is recognised not all approaches are interchangeable between the geographies. Certain US practices are less common in the UK and vice versa.

The Guide further draws on the model templates published by the British Private Equity & Venture Capital Association (BVCA), as well as further publicly available resources from prominent bodies including the National Venture Capital Association (NVCA), Research England (prepared by IP Pragmatics), the Association of University Technology Managers (AUTM) and others.

Looking to the future, we expect the USIT Guide to be updated from time to time to reflect the changing landscape of university ecosystems, the availability of capital and the evolution of best practice.



1.3 What do we Mean by University Spin-out Investment?

Most universities carry out research alongside the teaching of students. Universities and their researchers are committed to delivering a positive societal impact from their research.

Most universities carry out research alongside the teaching of students. Universities and their researchers are committed to delivering a positive societal impact from their research. One way to achieve this is through commercialisation, which involves protecting the intellectual property in the discoveries (often in the form of patents). A recent high-profile example is the Oxford-AstraZeneca Covid vaccine, which saved many lives and was pivotal in the global fight against the coronavirus.

One option for commercialisation is licensing to an already established company. This involves identifying external technology-based companies for which the discoveries can make a real difference. This can be by improving the products and services they sell, or improving their operations. The discoveries are licensed to such companies for them to use, typically with some payment back to the university and inventors in the form of royalties or milestones (pre-agreed targets that are crucial to the valuation of the company from the perspective of the investor). Another option for commercialisation is licensing to a newly formed spin-out company. This may the case for leading-edge discoveries, where there may not be an alternative company able to immediately apply the new technology. More often, however, it is the academic inventors' entrepreneurial ambition that drives the creation of a spin-out company to develop and exploit the IP. Funding for such companies is unlikely to come from product sales, which are many years away. Instead, investment is required – typically from venture capital investors, to provide the runway (coverage of operating costs) to develop the product to the point of revenue generation. It is this area on which the USIT guide focuses.

The formation of a spin-out company from university research typically follows the model shown in the diagram opposite.



Once the technology's commercial potential is identified and its inventors express a commitment to forming a company, the spinout can be established. The interplay between university, spin-out and investor can be described as follows.

- The university has a founding shareholding in the spin-out (formation equity) in recognition of the innovation ecosystem developed by the university, the role it plays as an employer and operator of the lab and research infrastructure, and the support it offers academics to develop the technology and business such as proof-of-concept funding, business plan development, investment, team building, etc.
- The spin-out secures rights to exploit the university's intellectual property (IP) usually through a licensing agreement with the university.
- The spin-out receives investment funds from investors and, in return, the investors secure an investment shareholding in the company (investment equity).
- The academics and researchers receive founder equity in the spin-out. The academics and researchers typically retain their employment with the university to continue their research and teaching duties. In such cases, the roles of the academics and researchers in the company are defined through consultancy agreements. Some researchers may choose to leave the university to join the spin-out as full-time staff members, in which case consultancy agreements are not required.

1.4 The Role of Universities in Spin-out Formation

A university's innovation policy framework encourages the academic community to participate in and be rewarded for their efforts in innovating. As such, policy frameworks must address equity stakes, royalty rates, opportunities for consultancy, terms under which the university can be a shareholder, and the financial sustainability of innovation within a university.

A university's innovation policy framework sets the tone for the university's role in enhancing the entrepreneurial pathway. Universities enhance the entrepreneurial pathway by offering support to academics that includes:

- Salaries for academic founders whilst working on/for spin-outs;
- Upfront financial and resource costs of IP protection;
- Use of labs and specialised equipment during, and often after, spin-out formation;
- Introductions to important networks e.g. mentors, investors, customers and service providers;
- Support in the creation of an effective business model;
- Support in technology due diligence;
- Leverage of the university brand for negotiation with customers and investors;
- Shared income from intellectual property licensing with employees, and
- The option of forming consultancy relationships with the spin-out.

1.5 **Spin-out Capitalisation Table** Cap Table

The distribution of shares in the spin-out is typically structured as shown in the diagram below. Before receipt of investment (pre-money), the shares are distributed between:

The distribution of shares in the spin-out is typically structured as shown in the diagram below. Before receipt of investment (pre-money), the shares are distributed between:

- i) The university formation equity;
- ii) The academic inventors (academic founding equity), and
- iii) An option scheme for the current and future employees of the spin-out (spin-out team options)

When the spin-out receives investment from an investor, additional shares are issued and distributed to the investors (investment equity), diluting the equity of the existing shareholders.

At each additional investment round, more shares are issued to the investors putting new money into the company. This further dilutes the existing shareholders.

Ideally, the company gains value during the course of its development. So, whilst the existing shareholders own a smaller percentage stake in the company after each investment round, the price per share and aggregate value of their shares continue to rise.

University Formation Equity (10-25%)		Academic Founding Equity				Spin-out Team Options	
			100%)			
st-Money Co	apitalisation Tabl	e					
University Formation Equity	Academie Founding Eq		Spin-out Team Options		First Investment Equity		
100-X%					Х%		
cond Investi	ment Round						
JFE Academic Fouding Equity STO			First Investment Equity		Second Investment Equity		
100-Y%)			Υ%		

Pre-Money Capitalisation Table

1.6 University Ecosystems are Wider than Spin-outs

Many universities describe the entrepreneurship and innovation landscape they operate in as an 'innovation ecosystem'. An ecosystem can be defined as a complex network or interconnected system, aimed at optimising the collective benefit for the participants in the system.

An ecosystem with a variety of participants is necessary for the effective translation of university research into economic and societal value.

The participants include idea-generators (university researchers), a translation mechanism (technology transfer office), translational funding, early stage and future investment, support services (legal, financial, IP), workspace providers, clients, management talent, a skilled workforce and effective communications. The symbiotic relationships between these participants are generally loose and fluid, without a single partner controlling the ecosystem.

One measure of success for any innovation ecosystem is the creation of companies that flourish and deliver both societal impact and economic value. The growth of the ecosystem is a goal for many universities, with attention focused on co-location of the participants, availability of seed and growth capital, and a range of location options for growing companies. An important challenge is to attract talent in all its forms, for example:

- Academic researchers and students to create new ideas, technologies, and services;
- Management talent with experience of growing spin-out companies;
- Technical services, including IP and legal support, who are comfortable in the early technology development environment;
- Early and future investors with an appetite for risk to support spin-outs in the ecosystem, and
- Local support services to help these new companies achieve their growth plans.

Finally, all innovation ecosystems need local and national government to provide incentives to locate new companies in the region and to support them effectively.

1.7 How Should the USIT Guide be Used

The USIT Guide is intended as a frame of reference to guide all UK universities that are forming venture-backed spin-outs, all academics and researchers embarking on a spin-out journey, and all investors who wish to invest in UK university spin-outs

By utilising the USIT Guide for the first stage of negotiations, it is hoped that many rounds of back-and-forth negotiation can be avoided - saving time, energy and money, whilst also preventing deal-scuppering disagreements. Instead, that energy and time can be devoted to the development of the spin-out and the technology.

The USIT Guide may also be useful for new practitioners in universities, spin-outs and investors, as they seek to improve their detailed understanding of commercial and legal terms. University administrators may consider the Guide as a basis for refinement of their policies, as they seek to maximise the generation of impact from academic research.

Research funders may refer to the USIT Guide as a way to set expectations for the economic return on the commercialisation of their funded research. They may also find the Guide a useful tool to evaluate specific deals. In many cases, universities require consent from research funders before they can commercialise a new technology. As such, the Guide may allow research funders to make consent-tocommercialise decisions more quickly. The USIT Guide incorporates the understanding that all spin-out formations and investment rounds are different and that there will be occasions when the optimal terms for the deal sit outside of the USIT Guide. In such cases, the Guide can still play a role as a baseline from which deviations can be explained, so that variances are understandable to all parties.

Variances may be driven by differences across sectors. The USIT Guide originated with the life sciences sector in mind, where product development times are long, regulatory environments are complex, R&D costs are high and effective patent protection can be lower than other sectors. Nevertheless, the USIT principles will still be transferrable to sectors where characteristics may be different. 02

Real World Examples of UK University Spin-out Investment Deals

1



2.1 Case Studies Illustrating the Life of a Deal Anonymised

2.1.1. Case Study 1

The technology transfer office (TTO) of a UK University worked with an academic to translate a key finding from their research into a drug development spin-out company. The invention had been protected by a patent filed by the university's TTO, but required third-party IP to allow development of the proposed product. The licence had commercial exclusivity, but permitted ongoing academic work.

Working with a venture capital fund, the TTO incorporated a company. The patent and associated know-how was licensed from the university to the newly formed entity in return for:

- i) Repayment of incurred patent costs amounting to approximately £50k;
- £1.0 million of equity in ordinary shares: 67% going to the founding academic, 33% to the university (a proportion of which would be shared with the inventors, founders and their department in the event of an exit);
- iii) Milestone payments totalling £1.0 million during the period up to and including first regulatory approval, and
- iv) A net royalty rate of 3.0%.

The incoming investor and the TTO's seed funds invested in non-participating preference shares with no dividend and no anti-dilution rights. The significant investment (over £10m) was divided into three tranches priced equally, with subsequent tranches dependent on the company meeting pre-specified milestones. Costs incurred by the investors and the TTO in setting up the company were reimbursed by the company at completion.

At incorporation, a member of the TTO was appointed to the board, alongside the academic founder. A TTO member can provide guidance to the founder in building an early-stage company, and help establish an appropriate strategy and corporate governance framework. They can also support effective interaction with the university or other research institutes. In this case, the founder did not become an employee of the company but established a consultancy contract to provide ongoing scientific input. III-health meant this was terminated a couple of years after funding. The founder's departure did not impact their equity shareholding, as they were deemed to be a good leaver (as defined in their contract).



The company made good progress and raised significant additional funding. The value of the university's equity stake increased, but the percentage of the total share capital reduced to low single digit. Four years from incorporation and after the Series B round, the academic founder and TTO representative stood down from the board but maintained information rights (a contractual requirement for the company to provide ongoing information to them).

After the successful demonstration of early clinical proof-of-concept, the spin-out was acquired by a large pharma company. The valuation was considerably above the total amount invested in the company and so all shares, both ordinary and preferred, enjoyed the same economic rights. With a 0.31% equity holding, the university could vote on the exit, but could not veto its completion once a majority of the shareholders had agreed. The university continues to benefit from the economic rights associated with the licence (i.e. milestones and royalties).

The process provided many benefits. The academic's research has been translated into a product in clinical development that is being investigated as a first-in-class treatment for a condition with significant unmet medical need. If the clinical trials are positive, the novel drug will have a huge societal impact for patients who currently have very limited treatment options. At acquisition, the company had 160 employees, the majority in the UK, supporting the economy and the broader life science community. And, although the university and the founders were small minority shareholders at exit, they each received several million pounds.

2.1.2 Case Study 2

The spin-out built on 15 years of fundamental research, coupled with an idea to apply the results of that research in a novel space to treat a potentially wide range of health conditions. The academics recognised that the best way to advance their research such that it could be trialled in the clinic and applied, if successful, was to found a company.

The creation of the company came through a series of friendships and partnerships, and benefitted from a healthy biotech ecosystem surrounding the university. The university technology transfer office worked with the academics to protect the IP assets and represented the founder academics in negotiations. The founders were introduced to an individual with contacts in industry and extensive experience in life sciences spin-outs, who became their mentor and acted as Chair of the spin-out from founding to exit. The founders were supported through the spin-out process by a local venture capital investor which is partnered with the university. The local venture capital investor dedicated an experienced biotech investor to the project in the role of 'entrepreneur in residence' (EiR), who worked with the company to develop detailed business and funding plans and an understanding of the markets and regulatory pathways.

It took approximately one year from initial discussions through protection of IP, design of a solid business plan, and successfully sourcing funding, to the formation of a fully funded spin-out. The company was created with 5 founders, including the mentor, who was appointed Chair, and the EiR, who was appointed CEO. At incorporation, the founders collectively held 50% of the equity, with the university holding 50%, which was split with the local venture capital investor under their partnership. The initial funding round diluted the holders of founding equity, and comprised commitments of c. £15m from the local venture capital investor and a US venture capital investor, tranched against milestones over several years. The company was also given the ability to extend the round by a further c. £10m, which would enable it to bring in other investors. The initial board comprised the Chair, one founder director and two investor directors. Spin-out costs incurred by investors and the technology transfer office were reimbursed by the company once it had received its initial funding.

A licence agreement was entered into with the university. On signing, the company reimbursed patent costs and paid a c. £50k signing fee. Royalties are payable on net sales in a range of 0.5-1.5% depending on relevant patent coverage, and are triggered by a cumulative £25m net sales threshold being met. Success milestones were payable on IPO and exit in a range between 0.5 and 2% of the company's valuation, up to a maximum of £5m.

Not long after seed funding, the company attracted interest from two other US venture capital funds, and the seed funding deal was recut, resulting in a c. £25m Series A funding round, tranched against milestones, with the original and new investors participating.

The company grew rapidly after launch. It was initially based in a university incubator space, then moved to a dedicated site on a local science park. Appointment of an experienced CSO was key to the company's successful development, and some of the students involved in the research at the university decided to join the company. A share option plan was introduced, with a pool of up to 15% of fully diluted share capital, which was expanded at each funding round to maintain the total pool at 15%.

The company was advancing towards Phase I clinical trials and required additional financing. The original investors all participated in the Series B funding round, alongside two new investors. A further c. £80m was raised, again tranched against milestones.

After the first tranche was advanced, but before the Series B tranche 2 milestones were met, the company received an approach from a large US pharmaceutical company. A period of intense negotiation resulted in the company being acquired for a total cash consideration in excess of \$400m, approximately four years after it was spun out from the university. With a 0.15% equity holding, the university received low double digit millions on exit, including a licensing milestone. The company's operations have stayed in the UK, and the founders remain with the company. The acquisition has enabled the company to expand and accelerate its clinical trials programme, and Phase I clinical trials are now well underway.

2.2 Case Studies Illustrating Successful Companies Named

2.2.1. Freeline Therapeutics

Using research developed at UCL's Cancer Institute, Freeline Therapeutics is developing new gene therapies which use a 'plug-and-play' approach to treat disorders including haemophilia B, Fabry and Gaucher disease.

Inherited genetic disorders can have an enormous negative impact on a patient's life. Diseases like haemophilia and Fabry disease are debilitating and require patients to undergo regular injections, usually for life. Others can be life-threatening. Gaucher disease and other Lysosomal Storage Disorders (LSDs) mostly affect children, many of whom die at a young age. But now, significant advances in gene therapies are opening up the prospect of curative treatments for these devastating diseases.

Freeline Therapeutics is one of a new breed of biopharmaceutical companies pursuing the challenge of safe and effective therapies for patients with genetic disorders. The company was spun out from UCL Business (UCLB) in 2015, based on work done by Professor Amit Nathwani.

Syncona, a UK based VC, made a substantial Series A investment of £25 million in 2016. That same year, the UCL Technology Fund (UCLTF) also invested £1 million. Once set up, UCLB licensed a suite of IP to Freeline, including novel gene therapy treatments for Haemophilia A, Fabry's disease and Gaucher's disease, as well as an ultra-efficient novel adeno-associated virus (AAV) serotype. A further \$218 million was raised in subsequent fundraising rounds. An initial public offering on the NASDAQ stock exchange followed in 2020, raising approximately \$162 million.

These investments have allowed the company to invest in a manufacturing facility, alongside its R&D laboratories in Stevenage. The facility allows the company to produce clinical-grade products without concerns about bottlenecks or quality and enables the rapid progress of multiple programmes through pre-clinical and clinical phases.

The technology uses the new virus vector to get functional copies of missing or mutated genes directly into a patient's cells. Newly synthesised proteins are then released into the blood. Crucially, it can achieve long-lasting effects from a one-time infusion using this novel AAV serotype.



Data from the new approach was impressive, with Freeline's haemophilia B gene therapy now able to normalise Factor IX levels (a vital enzyme for blood coagulation), allowing patients to lead normal lives. It also opens the door to creating treatments for other diseases, including Fabry, and Gaucher disease.

The first patient in Freeline's lead programme in haemophilia B was dosed in 2018. A second programme in Fabry disease entered the clinic in 2019, and a third clinical programme, in Gaucher disease, opened in 2022.

→ www.freelinetx.com

2.2.2. Refeyn

Refeyn uses mass photometry, a ground-breaking new scientific technique, to weigh molecules using light. Spun out by Oxford University Innovation (OUI) in 2018, Refeyn develops and manufactures mass photometry instruments, which have quickly been adopted by pharmaceutical and academic research labs around the world. Among its many applications, this technology has seen use in COVID-19 research. Thanks to the technology's success, Refeyn has grown to be worth over \$250m.

Refeyn started life in Professor Philipp Kukura's group at the University of Oxford, where they had been working on interferometric scattering microscopy (iSCAT) for almost ten years. In a 2014 breakthrough, the group demonstrated that iSCAT could be made sensitive enough to detect individual proteins without the need for protein-modification through the addition of fluorescent marker labels which could potentially alter the results. In 2018, they showed that, in addition to detecting individual proteins, iSCAT could also be used to measure their mass – and mass photometry was born.

OUI, the technology transfer office for the University of Oxford, proved instrumental during both pre- and post-company spin-out, aiding in the protection of the initial disclosure and managing the IP. OUI helped raise translational funding via its Impact Accelerator award scheme, helping to prototype an instrument for display at trade fairs. It also brought Refeyn together with investors, including Oxford Science Enterprises and Parkwalk, to provide seed investments. To quote Matthias Langhorst, Refeyn's Chief Product Officer:

'As we established and grew the company, we found we could always rely on OUI as partners in administering, prosecuting and expanding our IP portfolio, and this was critical to our business's success... Building on our partnership with OUI, we were able to secure a substantial investment first in our Series A funding round in 2020, and then again in our Series B round in 2022.'

OUI has been directly involved in the running of Refeyn, taking an active board role and investing in all of the funding rounds, contributing to the continued development of the 'mass photometry revolution'.

→ www.refeyn.com



2.2.3. GammaDelta Therapeutics

GammaDelta Therapeutics ('GDTx') was founded on pioneering research into gamma delta ($v\delta$) T-cells, by Professor Adrian Hayday and Dr Oliver Nussbaumer at King's College London and the Francis Crick Institute, funded in part by Cancer Research UK. These are a unique and conserved population of lymphocytes that contribute to many types of immune responses and immunopathologies. The new company was focused on exploiting this work to develop improved immunotherapies for cancer and potentially other diseases.

In August 2016, Abingworth, a bio-science investment firm, seeded the company in its London office with a £0.8m investment. Abingworth then negotiated the licence agreement and shareholder agreements with the three institutions and played a key role in raising the next round of Series A capital.

In May 2017, GDTx entered into a research collaboration and option agreement with Takeda Pharmaceuticals. Takeda committed \$100m to accelerate GDTx's programmes. The agreement included an equity investment, an option fee and R&D funding and provided Takeda with the option to acquire GDTx for an undisclosed sum. Overall £30m in equity investments were made. Abingworth brought in the Chairman, key board members and advisors, plus senior management and helped define the science and business strategy.

GDTx made a small acquisition of a company in a similar area called Lymphact. This has added a blood derived gamma delta T-cell variant to the core tissue derived product. Abingworth was also instrumental in the spin-out of Adaptate Therapeutics from GDTx for which all the GDTx investors, including the institutions, received shares.

In October 2021 Oct '21 Takeda exercised their option to acquire GammaDelta Therapeutics and early in 2022 also agreed to buy Adaptate. The financial returns were very attractive to all shareholders, including the institutions.





The USIT Guide's Recommended Terms

3.0 Recommended Terms

This section presents a detailed collection of recommended terms for consideration when setting up spin-outs and licencing university IP and have been arrived at after extensive consultation with university, VC, legal and commercialisation communities and stakeholders.

The following sub-section 3.1 represents a brief summary of the terms. Sections 3.2 and 3.3 cover each term in detail. Particular metrics were considered in the context of the life sciences sector. Product development and go-to-market timelines, regulatory environment complexity, R&D investment required, IP protection duration, operation/business risk levels, product profitability, returns potential etc., are all sectorspecific characteristics that need to be taken into consideration. As such, some of the financial details herein may be different to those observed in other sectors, nevertheless the recommendations and approaches described are applicable to many sectors and are intended for guidance and to drive discussion. They do not replace negotiation and a clear rationale for a chosen approach. Terms are inter-related and connected, they should be agreed according to the specific situation of all parties and in consideration of the whole deal in totality. Terms should be drafted by qualified legal professionals.
3.1 Summary of Recommended Terms

Term Sheet (Start-up formation)

- Total Deal Value: The terms of i) the investment and shareholdings for spin-out formation and ii) the terms of the university-derived IP licence are heavily related, with each countering/enhancing the other. Together they reflect the deal's (perceived) value, however equity entitlements and IP licence terms are ordinarily codified via separate agreements. They may be negotiated by separate university teams.
- University Equity: Universities take an equity stake in the spin-out for a variety of reasons. The valuation of a university spin-out can vary; however, pre-money valuations should always be based on a clear rationale. For spin-outs with little IP or other assets, more equity will typically be held by the founders than the university. Where spin-outs have more university-derived IP and assets, more weighting is given to the university's founding equity positions. University founding equity is commonly within the range of 10% - 25%, though university founding equity can be outside this range in certain circumstances. Most investment rounds will dilute the founding equity holders proportionally to their shareholdings. In some cases, the university holding may be protected from dilution to a certain point, in which instance the university founding equity is outside this range, commonly below 10%. In some instances where an investor is willing to invest to de-risk an early project, advanced subscription agreements (ASAs), simple agreements for future equity (SAFEs) and/or convertible notes may be used. This delays the setting of a valuation to a later point and may enable quicker access to funds.
- Share Type: A single share type for founders, employees and investors can be advantageous to align parties. However, investors often seek a different class of share. This is most commonly a non-participating preference at a 1X multiple.
- Employee Share Option Pools (ESOP): ESOP are to be created at a size in line with the specific needs of the spin-out for its next planned activity.
 5-20% of the fully diluted equity is typical, with most in the UK between 10-15%. Timing of ESOP creation can influence company valuation (postmoney vs pre-money) and valuations should be adjusted accordingly.
- Leaver provisions: Founders and key employees are often subject to good leaver/bad leaver provisions in order to retain shareholding-based incentives put in place to encourage desired behaviours. It is important to clearly define what constitutes a good or bad leaver, and triggers for each from the start.
- Investment Tranches: Smaller investment amounts (e.g. under £10m) may be paid as a lump sum. Larger investments (e.g. over £10m) may be paid in tranches linked to the business plan over a 2-3 year period.

- Pre-emptive Right / Participation Right / Right of First Refusal (ROFR) / Pro Rata: Existing shareholders (or sometimes just investors) usually have preemptive rights / participation rights / ROFR / pro rata but can lose such rights for future rounds (or slimmed down pro-rata to new holdings), if no investment is made in the present round and pro-rata holding ranges are not retained. Shareholders are usually allowed to transfer rights to 'permitted transferees', including affiliate investment funds and, in the case of universities, connected entities.
- Drag-Along and Tag-Along Rights: All shareholders to have rights where if any 'majority' shareholder has opportunity to sell shares resulting in a change of control, other shareholders are given the opportunity to sell their shares with same exit rights. 'Majority' is often defined as a shareholder of at least 'X' percent, negotiated between the parties.
- Board Seats: A university transitioning out of board should be determined by a balance between the university's equity position and the value they bring to the skills matrix. As a guide, it is common for universities to have board seat entitlement up to 'X%' (typically between 5% - 10% fully diluted) and then transition to observer status or information status, unless asked to maintain its board seat, once the university shareholding falls below this range.
- Transaction Fee / Legal Costs / Monitoring Fee: Parties bearing their own costs is a fair approach, incentivising a swift and focused transaction. Alternatively, a spin-out may pay investor legal costs, with payment made at deal completion when incoming investment is received. Where the university uses outsourced legal counsel, the spin-out should also offer to pay the university legal costs. Monitoring fees are not usual, with the exception of venture capital trusts.
- **Transaction Timeframes:** Faster timeframes for deal completion are strongly encouraged to reduce the cost of transacting and increase spin-out formations across the ecosystem, with under three months a preferred target timeframe.
- National Security & Investment Act 2021: The National Security and Investment Act gives the government powers to scrutinise and intervene in business transactions, such as acquisitions of spin-outs, to protect national security. The act provides for a mandatory notification regime where a third party takes ownership of over 25% of shares or voting rights in a company operating in 17 specified sectors such as quantum technologies and synthetic biology. This can have significant impact where the university takes over 25% and expert legal advice is recommended.

Heads of Terms (Licence Agreement)

- Royalties and Success-Based Milestones: Royalties and successbased milestones should be set using technology valuation appraisal methodologies and benchmarking comparators, appropriate to business plan and in line with market rates. Balance the spin-out's need to preserve early cashflow and back-weighted licence against the university's need for early returns. Some fee ranges have been included for reference purposes only, with focus on optimising an integrated deal.
- Windfall Success: These are payments due when a spin-out achieves valuation-based milestones and/or a liquidity event. They may be linked to exit fees and/or synthetic equity and can be considered as part of a mixed approach to achieve a net financial position, where unconventional licence structures are negotiated. As such, it is important to consider windfall success payments in conjunction with equity and licence fees. This mechanism is rarely used in the UK, and whilst it has some advantages, windfall success clauses are often difficult to draft and implement.
- Other Products / Enabled Products / Licensed Know-how & Technical information: Licensed know-how underpinning enabled products should attract lower licence fees. Agreements should list specific know-how items, carefully define enabled products and cap academic support for reducing know-how to practice (typically two days).
- Licensing Improvements: For a time-bound period (often two years), the university usually offers the spin-out a licence to narrowly defined, university-generated improvements of the earlier-licensed university IP, where feasible. This may be an automatic addition to the existing licence, through the inclusion of an option clause in the existing licence, or through the execution of a separate option agreement which in either instance if the option is exercised, can lead to negotiation of new commercial terms relating to the improvements and execution of a separate licence agreement.
- Field of Use / Diligence Clauses / Minimum Royalties, Annual Payments / Mandatory Sub-Licensing: Field scope should be sufficiently broad to support the business plan, with diligence conditions and reversion rights where the spin-out is unable to achieve diligence milestones. Escalating annual royalties and/or maintenance fees can work to achieve right balance of granted rights and may incentivise the spin-out to release non-developed licensed IP. The appetite for possible future IP assignment to the spin-out will be university specific.

- **Sub-Licensing:** The sub-licensee is to be bound by head licence key terms and the licensee should notify the university prior to executing the sub-licence.
- The licensee will usually:
 - → be limited in sub-licensing tiers (commonly 1 unless otherwise agreed);
 - → be obliged to pay head licence royalties, milestones etc., irrespective of whether the licensee or sub-licensee achieves them, (unless particular technology or start-up circumstances cause for an alternative negotiated position);
 - → recognise other sub-licence amounts due (excluding R&D funding) as net receipts (sometimes not entirely synonymously referred to as non-royalty sub-licence income);
 - → have tiered (decreasing) net receipts percentages to encourage technology investment by licensee;
 - \rightarrow apportion relative contribution for bundled IP;
 - ightarrow be subject to floors for bundled / stacked IP;
 - → have a mechanism for dispute resolution, and
 - have a mechanism for managing the sub-licence when the head licence terminates, which may include mutual termination, commencement of a short negotiation period between sub-licensee and licensor or automatic allowance for the sub-licensee to take on the head licence (with potential agreement amendments).

Continued IP ownership can remain with the university where the spin-out is able to control ongoing strategy and prosecution, or IP can be assigned to the spin-out (post patent issuance) with an exit fee negotiated and reversion rights retained by university. In practice, these may be challenging to enforce.

• Patent Prosecution and Patent Expense Reimbursement: The university's incurred patent expenses up to the point of licensing are usually reimbursed by the spin-out. Thereafter, it is usual for the spin-out to lead IP prosecution.

SUMMARY OF RECOMMENDED TERMS

- **Reservation of rights:** The university will reserve rights (perpetual, worldwide, royalty free license) for academic research and teaching purposes. Ongoing debate exists on best practice to approach a university's reserved right to include clinical research and research with third-party industry sponsors.
- Indemnities: Indemnities, warranties and liabilities are to be considered collectively. It is usual for the spin-out to indemnify the university (and TTO), except where the university has wilfully breached the licence agreement.
- Warranties: Minimum warranties are ordinarily provided by the university and are knowledge-qualified where possible and relevant. The university will also ordinarily require the spin-out to give assurances it has all the relevant IP from the university needed to exploit the technology.
- Liabilities: Within the IP licence, limitation of liability is commonly capped (e.g. £10k-£50k). Licensees must have suitable insurances.
- Ethical Licensing / Global Access: The spin-out will be prohibited from sub-licencing to proscribed entities. Global technology access is recognised as a 'nice to have' and may be provided for under certain circumstances (pending the technology type, environmental situation and potential burden on spin-out), though, in practice, it is often difficult for the spin-out to oblige. Certain obligations may be voluntarily agreed by Parties or mandated by the original funder or university policy.



3.2 Term Sheet Spin-out Formation

3.2.1 University Equity

Note: This clause relates to university equity only. Academic founder's equity may be addressed:

i) directly with the academic founder;
ii) through pre-agreed university policies; and/or
iii) through ESOP allocations.

Academic founding equity should be proportionate to university equity to incentivise founders. At commencement, the spin-out company will be incorporated with the shares held entirely by the founders (for tax reasons, and subject to the universities' conflict of interest policies). The equity split between the founders and universities is then determined and 100% of equity is owned by the university and founders, with possibly some equity holdings for research funders. This is the pre-investment position of the company. With the preinvestment (pre-money) valuation undertaken on a case-by-case basis, the equity position of the university post-investment will vary.

There are multiple reasons why the university might take an equity stake at the time of spin-out formation. They can include (and are not limited to):

- Recognition of university support given previously (and continuing for the technology, academic founder's and academic company staff development;
- Ability for the spin-out to leverage university resources, (including to enable the spin-out formation itself) and facilities;
- The ability for spin-out to leverage the university brand;
- Further motivation for academic staff involved in the spin-out who may benefit directly (by a return to the individual) and/or indirectly (by a return to department or university) from the university's shareholding (via university policy);
- Access to university connections, including investors, management teams, etc., through their technology transfer offices - bringing smarter risk-taking, expanded talent pools, and increased potential for innovation;
- Added flexibility for the university to amend certain licensing clauses, including revenue bearing clauses;
- · Spin-out governance support and consent matters, and
- Compliance reasons (funders, government etc.).

Division of Shares Between Founders

How academic founders (professors, researchers, postdocs etc.) allocate shares amongst themselves is a question that sometimes arises. While the USIT Guide is focussed on the university-VC transaction, with guidance for academic founders outside the USIT Guide scope (indeed, academic founders should seek independent advice), it may be useful for founders to consider how equity could be used to 'reward for past activity' and/or 'incentivise future activity'.

Founders may wish to differentiate between equity that is allocated to reflect contributions leading up the spin-out's formation, and equity allocated to founders who will continue to be actively involved in the spin-out. The former is often a feature of the university's equity, where returns to university staff are realised through the university's own revenue share policy (most often based on returns generated through licence fees). Alternatively, more 'passive' founders may simply be allocated fewer shares than founders who will actively continue in operations. Active founders may be allocated more equity than the less active founders and may also be incentivised to 'earn' additional shares via clawing back founding shares, topping up founding shares or earning shares via the ESOP over time (see below). It should be noted founding shares may be more tax efficient for founders than earning shares via ESOP, as shares will likely be issued at 'par' value from the start

Whichever approach is adopted, it is important that honest, transparent and justifiable conversations on equity allocation amongst founders are had to ensure fair and mutually agreeable positions are arrived at for all.

Pre-Investment University Equity

Almost always, more pre-investment equity will be held by the founders than the university. For spin-out companies with little IP or other assets, the equity will be weighted in favour of the founders. On the other hand, spin-outs with more mature technologies and a portfolio of IP or other assets, the weighting of the equity allocation to increases in favour of the university.

Starting (founding) equity percentages for the universities between 10-25%¹ are typical. That is, before any dilutive third-party investment, the university share of the equity in the spin-out company is typically 10-25%. The remainder is shared with the academic and other founders.

Pre-investment university equity positions outside of this upper range do occur, i.e. over 25%. Examples include where the university is holding equity for founders or funders, the university is receiving low or very low licence fees, or some other reason. In certain circumstances, university equity positions below this range may also occur, i.e. under 10%, where the company might have a revenuebearing licence with higher licensing fees.

¹ While pre-money university equity positions within the range of 10% - 25% dilutable equity are typical, UK universities are working to further align and narrow the typical range, aiming towards a midpoint within this range over time.

The valuation of a university spin-out company can vary considerably. Many factors can impact valuations. These include the extent, type and novelty of IP, technology readiness level, estimated time to market, management team's expertise and track record, the size of the commercial opportunity, the size of investment required, the competitive environment, and so on.

In order to ensure a fair valuation, it is recommended to undertake detailed comparator due diligence prior to accepting a term sheet for investment into a spin-out company. The valuation is used to establish the spin-out's pre-money valuation. This pre-money valuation should be based on a clear rationale.

Sensible company valuations undertaken upfront will justify respective starting positions for equity negotiations and help ensure smooth and speedy discussions.

Used often in US and APAC, advanced subscription agreements (ASAs), simple agreements for future equity (SAFEs) and/or convertible notes are becoming a common feature of the UK venture landscape. These instruments are used at a stage in the spin-out where investors seek to invest, but the company is at too early a stage to set a meaningful valuation, yet still requires funding to progress to its first priced round. The ASAs, SAFEs and/or notes convert into equity at the first equity investment round and allow the investor to receive equity at a discounted price at the next round. They will often include a valuation cap, that is, the maximum valuation at which the notes convert into equity. Lower valuation caps benefit the investor, higher valuation caps benefit the spinout (for example and illustrative purposes only, if an investor invests £100,000 and the spin-out is later valued at £1,000,000 then the equity is 10%. If the same investment is made and the spin-out is later valued at £10,000,000, then the equity is 1%). These instruments have advantages and disadvantages, both of which should be recognised when considering using them in lieu of an upfront company valuation.

Dilutive vs Non-dilutive Equity

In the majority of investment rounds, the percentage of the founding shareholders' equity will be diluted proportionally to their shareholdings. The actual number of shares each founder holds will not reduce.

In some circumstances, the university's holding can be protected from the dilution associated with an equity investment round. This may be absolute, e.g. the university remains at 'x'% (e.g. 10% or less) of the total equity, or capped, so as not to fall below a specified percentage. Where such approaches are adopted, they will tend to fall away on pre-specified milestones being met, e.g. a fundraise of a certain size.

remaining pre-money equity is held by shareholders. These are made up of founders, potentially funders, and potentially a provision for an ESOP. Founders, who can be university employees or non-university employees, may take direct equity in the spin-out company (it is recommended that academic founders take specialist tax advice to minimise their future tax burden, but this falls outside of the scope of this guide²). Alternatively, the university's equity position may include equity held on behalf of university inventors/founders, and potentially some research funders, who are not taking equity directly in the spin-out company^{3,4}. To accommodate the university holding equity for other parties, the initial university equity position may be larger.

We recommend the universities have a clear and transparent (and ideally published) policy on the allocation of equity between the different stakeholders, (e.g. university, department, inventors, founders etc.), which should be factored into negotiations and recognised as part of the spin-out company's term sheet.

Equity and licence fees are interrelated and should be considered collectively when negotiating the formation of a spin-out company with investors. Higher licence fees may offset lower equity holdings or vice versa. Additionally, most universities will have their own IP and spin-out policies and these should also be recognised when negotiating the formation of a spin-out company.

A university may wish to include a 'change of control', 'exit fee' or 'synthetic equity' clause in lieu of, or in addition to, a university equity holding. Such clauses can be linked to a valuation paid by third parties at a change of control event or at an acquisition event of the spin-out. They may be included in the term sheet or feature as a condition in the licence HoT. (See also Windfall Success 3.3.2 which can also be linked to exit fees/synthetic equity). However, consideration should also be given to the situation that the spin-out does not exit.

Where included, a low, single-digit percentage (e.g. 1–3% of change of control/ exit proceeds) or alternatively a set fee for change of control/exit payable by the spin-out, is typically negotiated. An agreed trigger mechanism should be clearly defined, e.g. a qualified IPO. These types of clauses are not common in the UK university spin-out ecosystem.

² It is often beneficial for UK founders taking direct equity to enter into 'section 431' tax elections – it is recommended that founders take specialist tax advice on this and the wider structure.

³ University policy may state all academic inventors/founders who have contributed to the licensed IP are entitled to equity in the spin-out company. The actual allocation of equity entitlement will be determined by the university policy and will likely differ between universities. Conceptually, the university IP policy rewards the individual academic inventors for their historic work in creating the IP licensed to the spin-out. The conceptual justification for founders' direct equity is quite different – it is to incentivise and reward the founders for their involvement in the spin-out company, going forward. It is not a reward for past achievement. Some universities do require founders to waive their entitlement under the university IP policy if they receive direct equity, though this is rare and is arguably misconceived for the reasons set out. The university could consider making their policy available to stakeholders (investors, other non-employee founders) so the university's position is understood from the outset.

⁴ Note that the licence generally represents the interests of inventors within the university, rather than founders who may not necessarily stay or be affiliated with the university. It is not uncommon for a university to request the academic inventor opt out of receiving a share of licensing revenues received by the university if they have direct founding equity in the spin-out. However, there are variances to this approach, including where academic inventors may be able to share in both equity gains directly as an academic founder, as well as licence fee gains via the university's position. Where an academic founder holds direct equity, it is advised independent legal advice be sought.

It is to be emphasised that the university's equity holding is a single lever within a wide range of elements to be considered. Licence fees will impact equity holdings and vice versa.

There are several factors and levers which can be varied to allow founders to modify the equity proposition as the license transaction is considered in its entirety.



These levers are tools through which a deal can be optimised for all parties to get the right deal for the company, the investors and the founding institution.

Each lever can't be moved in isolation – it needs to be considered in the context of the overall deal. Some high-level examples of applying levers are outlined below.

- A spin-out wants to avoid early licence fees (e.g. upfront payments, annual fees), and would prefer reduced royalties or milestone payments. The university's equity would be at the higher end of the of range to compensate.
- A university has a preference for a low equity stake at founding (e.g. under 10%) and chooses to have non-dilute terms up to a defined subsequent investment threshold (e.g. Series A).
- If all the inventors are founders and they waive their rights under University IP policy, this can enable university equity to be reduced (potentially by up to a third).
- If the university-derived IP is critical to found the spin-out, this would normally result in university equity at the higher end of the range; if the university-derived IP is additive but not foundational IP this may result in university having equity at the lower end of the range.
- If there are multiple university inventors who are not founders of the company this may require an equity stake at the higher end of the range to protect the interests of non-founding inventors.
- If the funder of the research also contractually requires equity share, this often results in equity being at the higher end of the range.

3.2.2 Share Type

There are advantages for the founders, the university and investors to all receive ordinary shares in the spin-out company, as this can encourage alignment between parties and distributes risk evenly. All parties receiving ordinary shares helps to establish a team ethos with a transparent distribution of economic proceeds in the event of an exit.

While a single share type is preferable and should be sought, with the risks associated with early-stage technology, investors frequently seek or require a different class of share for their investment. Generally, the different share class will provide more protection than ordinary shares to the investor in the event of a negative outcome for the company. This provides a benefit for the investor not enjoyed by the university or founders.

For example, an alternative approach to all parties receiving ordinary shares is for founders and the university to receive ordinary shares, and for investors to receive preference seed or series A shares. Preference shares typically carry a liquidation preference, which will be either:

- A non-participating preference (normally at a 1X multiple): a liquidation preference, that protects the investor's investment in the event that the company is sold at a price that would yield a return (on a prorata basis) of less than the total investment made. For example, if the investor invests £1m into the spin-out company, they will be paid £1m before any proceeds are paid to ordinary shareholders, i.e. the founders, the university and employee option holders. If the share price at exit is greater than the share price at the time of the investment, then non-participating preferred shares are converted (or deemed to be converted) into ordinary shares and all shareholders are treated equally. In some instances, investors may also convert their shares into ordinary shares equivalent (e.g. at a conversion rate of 1:1) and receive a portion of the proceeds based on their equity ownership share, instead of their preference). Non-participating shares are an 'either/or' scenario.
- A participating preference (normally a 1X multiple): a liquidation preference where, upon an exit or liquidation, investors receive their investment back first and then all shareholders (both preferred and ordinary) receive a distribution of the remaining funds, in line with their percentage holdings. For example, if the investors invest £1 million in preferred shares with 1x participation, at a £5 million exit, the preferred shareholders will receive initially £1 million with the remaining £4 million distributed to preferred and ordinary shareholders according to their percentage overall holding. In extreme circumstances, higher multiples of participation can be introduced, e.g. 2X - 3X the investment amount.

A participating preference is a 'double dip' and is very uncommon in university spin-out companies, as it creates misalignment between the different stakeholders.

On some occasions, preferred shares may carry rights to a special or preferred dividend. This can act like interest on the investment for the investors, as often the spin-out doesn't have funds or distributable profits to pay a special dividend, and as such, they are rolled up and paid at exit. Special dividends are very uncommon in university spin-out companies.

3.2.3 Employee Share Option Pools (ESOPs)

The majority of spin-outs will establish ESOPs in order to facilitate recruitment, incentivise the team and to retain talent. The ESOP allows employees to benefit from the spin-out's success⁵. ESOPs are almost always granted over ordinary shares and will dilute the existing shareholders.

To optimise ESOP creation for a spin-out, it is recommended ESOPs be created only to a required size, determined by factors such as:

- Intended hires ahead of the next fundraising round (e.g. the number of employees required and the type/level of employees to get to the next inflection point, what share allocation is appropriate, whether share allocations can be tiered etc.); and
- The size of the investment amount (e.g. a £30m investment round may have a larger ESOP vs a £3m investment round, with the larger investment indicating more personnel required).

Example ESOP size ranges tend to be between 5%-20% of the fully diluted equity of the company, with most in the UK between 10%-15%. ESOPs can be larger if justified by bold, fast hiring plans with C-suite employees targeted.

To support ESOP discussions, consideration should be given to a hiring plan, e.g. how many hires are realistic ahead of the next fundraise? What share allocation is appropriate for employee types, and can these be tiered? Where the investment is tranched, the absolute number of shares in the ESOP typically expands with each tranche, while the percentage of the fully diluted equity remains constant. That is, ESOPs may be created/expanded from tranche to tranche.

⁵ There are a number of tax-advantaged share option plans available to spin-outs, which can provide a greater incentive to employees. Tax advice is strongly recommended to gain the best position.

It should be recognised that timing of ESOP creation can impact the valuation to different shareholders:

- Post-money ESOPs benefit existing shareholders (all shareholders diluted founders, universities and incoming investors).
- Pre-money ESOPs benefit incoming investors as existing shareholders are diluted before investors come in. The bigger the pre-money ESOP, the lower the effective valuation on a per-share basis. Additionally, if a reverse dilution later occurs (e.g. unallocated shares dissolve at exit) everyone benefits from this reverse dilution, despite only the original existing shareholders paying for the ESOP at time of creation). If premoney ESOPs are used, funding and equity models should be adjusted accordingly, e.g. a higher company valuation and/or a smaller ESOP.

When an ESOP is presented as part of the pre-money, the impact on valuation should be acknowledged and appropriately adjusted (i.e. ESOP creation post-money may bring about a lower start-up valuation. ESOP creation pre-money may bring about a higher start-up valuation).

Note: The issuance of shares to certain employees/directors can result in tax implications. Tax guidance is advised.

3.2.4 Good Leaver / Bad Leaver

The way that the founder's shareholding and the options are treated at the time of an individual's departure from the company are covered by good leaver/bad leaver provisions.

Good leavers will typically maintain their shareholding and/or rights to the options, while bad leavers will typically lose all or some of these holdings/rights. The circumstances where a leaver is considered a good leaver will vary, but generally include where an individual's employment is ended through no fault of their own, e.g. ill-health, redundancy, relocation, retirement, resignation by employee after required period of time, termination of employment by spin-out under positive circumstances (i.e. other than for cause), illness, disability or death.

Conditions where an individual is regarded as a bad leaver will also vary, but generally anyone who brings the company into disrepute, e.g. behaving in a way warranting summary dismissal, committing fraud, breaching confidentiality or their employment agreement, failing to fulfil their duties, resigning early, knowingly impacting spin-out value negatively etc..

The intermediary situations are often more challenging to clearly define (e.g. the spin-out may be at fault and a key employee wishes to resign early for other reasons). It is important to clearly define what constitutes a good or bad leaver from the start, and the relevant triggers for each on a caseby-case basis.

When an investor invests in a company, much of the value that they ascribe to the business is linked to the continued involvement of the founders. Consequently, they are keen to ensure that the founders are incentivised to stay involved with the company and to prevent them from establishing competing businesses. Therefore, the founders' equity holding will typically be subject to a vesting schedule where the founders will not receive their shares (or more typically, their shareholding will be 'clawed back') should they leave before a defined period of time. Common timeframes include:

- · Four years for life science/deep tech, or
- Three years for non-deep tech.

Leaver provisions are typically subject to a one-year cliff where no equity vests until the first anniversary, though at the end of year one, the whole year's equity vests. The rest of the shareholding vests on a straight-line basis (or may be monthly, quarterly or yearly) during the vesting period.

GOOD LEAVER / BAD LEAVER

It is common that good leavers are entitled to keep all their shares. Bad leavers will typically forfeit all, or at least their unvested shares. Converting the bad leavers shares to deferred shares is generally the easiest way to deal with forfeited shares. Other recognised (though very rarely used) compulsory transfer-based approaches may include:

- Obligations on founders/key employees to reverse, transfer and/or sell offered shares to the spin-out;
- The ability for the spin-out to have Leaver's shares offered to incoming (replacement) key employees;
- The ability for the leaver to retain some/all shares at leaving at an increasing proportion over time, pending vesting schedule, e.g. 10% p.a. up to max 50%; and
- Pre-agreed pricing of good leaver and bad leaver shares, given circumstances at the time of leaving (e.g. fair value or discounted fair value, also giving consideration to the spin-out's tax implications.

An alternative approach to determining whether good leaver or bad leaver provisions apply, is to deem all founders/key employees as bad leavers at spin-out commencement and subsequently earn good leaver status over a period of time, though this approach is also rarely used in the UK.

It is usual for founders and key employees to sign non-solicit and non-compete clauses. These are d esigned to protect the company and to ensure that proprietary information is not used to set up a competing entity. The terms of the non-compete are included in the shareholders' agreement (for founders) or contracts (for key employees). Non-compete clauses need to balance the individual's right to work in their field after they leave the company and the company's right to protect its proprietary position. Any restrictions will be time-limited and should only be restrictive enough and for a duration necessary to protect the legitimate interests of the company (and in accordance with UK employment law). For university spin-outs, it is important to preserve the academic's freedom to continue their research and right to publish, and careful consideration should be made to maintaining these rights.

3.2.5 Investment Tranches

In some instances, the company and investors agree that an investment may be tranched. Investment tranches are generally linked to a spin-out's business plan, to enable the achievement of its near-term operational goals. Commonly, there are two approaches for investment payments:

- Smaller investments (e.g. under £10m) may be paid as lump sum at time of investment completion,
- Larger investments (e.g. over £10m) may be paid as tranches with later tranches linked to performance milestones. It is common to have up to two additional payments beyond the first tranche.

Where tranching is used, it is reasonable for the spin-out to receive all tranches within a reasonable timeframe, most often 2-3 years or less. An investment round extending beyond this period is outside of standard industry practice and special consideration should be given to the price and number of tranches for longer investment rounds. Tranches spaced too far apart, or milestones targeting significant value uplifts, may impact the spin-out's cashflow and create financial risk, as well as unjustly giving the investor opportunity to purchase shares at a de facto discount (thereby unduly diluting the founders, university and option holders).

For example, if the spin-out is required to achieve a milestone that adds a substantial uplift to its valuation (e.g. a hit-to-lead drug discovery company receiving its next investment tranche at the first patient dosed milestone in four years' time), it allows the investor to invest, on today's terms, at a future point in time when the company will arguably have higher valuation and equity is likely to cost more. If the duration for tranched investment is expected to extend over a longer period, consider having later tranches at a higher price.

3.2.5

3.2.6 Pre-emption Rights / Participation Rights / Right of First Refusal (ROFR)

It is common for existing shareholders to have pre-emption rights/ participation rights/ROFR, which enable them to invest alongside later investors on the same investment terms. Note, there can be benefits for spin-outs of fundraising from existing shareholders and keeping the investor pool small.

When exercising these rights, it is recommended that the university investment stays within its pro-rata holding ranges at the time of the next round.

If the university doesn't participate in a given round, it may be that it can only participate in the next round if the percentage of shares it holds then is retained, otherwise it has no right to participate in future rounds ('use it or lose it').

The parties may aim to time-restrict these rights to avoid slow fundraising rounds (e.g. 14-30 days). Note: investors and founders will ordinarily have rights to transfer their rights to specified 'permitted transferees'. For universities, this may be an affiliate investment fund (or some other designee) and can be of particular importance as, in practice, it may be challenging for universities to take up pre-emption/participation rights/ROFR rights and/or maintain pro-rata rights for future rounds, due to scarce resources.

3.2.7 Drag and Tag-Along Rights

Drag/tag-along rights are considered standard terms⁶ and ensure that minority shareholders cannot thwart key company activities.

Tag-along rights allow a minority shareholder to sell their shares in the event of a company sale (or equivalent) on the same terms and with the same buyer as the majority shareholder. These apply where a shareholder's sale of shares results in a change of spin-out control, giving the other shareholders the opportunity to sell all of their shares with the same exit rights (that is, on same terms and at the same price).

Drag-along rights are contractual provisions that allow a majority shareholder to force a minority shareholder to sell its shares under the terms negotiated by the majority shareholder in the event of a company sale (or equivalent event). The drag-along rights are triggered when the selling shareholders exceed a pre-defined percentage of the total shareholdings. In some cases, further conditions may be defined. For example, the dragged shareholders may be required to provide to the purchaser representations or warranties (except as to title) or to agree to other terms. The trigger for invoking the drag-along provisions is to be negotiated, with a key driver being the investor not wanting to be dragged out of its own investment or at a value lower than expected. For minority shareholders, there may be concern about being dragged. Note: a right of first refusal (ROFR) could be negotiated, though if the minority shareholder can't afford to buy, this provision is of little benefit.

Drag and tag-along rights are commonplace, and it is important to understand the triggers for the events and when shareholders are expected to sell.

Note: In UK early-stage spin-out corporate documents, there is often no need for registration rights as they refer to a US IPO process and are more applicable as concerns to US investors (e.g. shelf / piggy-back-related rights). The British Private Equity & Venture Capital Association (BVCA) documents include provisions that can be used if needed.

⁶ While such rights can be beneficial for the university in they allow it to exit on the same terms and at the same time as the majority or triggering shareholder(s), they may also be unfavourable if an exit is not the university's primary driver. Universities commercialise for impact and a forced sale of minority shares may mean the university exits before realising potential (non-monetary) gains or leaves the start-up prematurely. However, universities recognise the need to be comfortable with Drag-Along and Tag-Along Rights, as investors generally will not invest otherwise.

BOARD SEAT

3.2.8 Board Seat

The university will often request a board seat and/or observer status to stay involved with the spin-out in the early stage of formation. From the university's perspective, this is driven by a need for information access, the ability to identify synergistic opportunities, leverage internal complementary infrastructure and resources, an opportunity for learning and training for less experienced university-based board directors⁷ etc.. Equally, the university is likely to have been closely involved in the technology development, spin-out and initial funding, and having a university-appointed board member can be helpful to the spin-out to problem solve and/or facilitate decision making. However, as the spin-out advances and the university's shareholding in the spin-out reduces, it may not be strategically relevant (nor in the best interests of the spin-out) for the university to remain in an active governance role.

The point at which the university transitions out of board should be determined by a balance between the university's equity position and the value they bring, rather than a fundraising level or specific series.

It is recommended:

- The university be entitled to board seat up to a defined % equity stake (ordinarily between c.5%-c.10%, fully diluted). Thereafter, for equity stakes less than this, the university should relinquish the board seat (unless asked to stay on) and transition to board observer status or move straight to information status, where the university is provided with realtime information from the spin-out (e.g. board meeting minutes within 30 days; periodic updates from the spin-out on specific points, periodic meetings etc.). In most instances, a university's need for spin-out oversight can be met through a combination of real-time information and solid diligence conditions in the licence.
- In board structures where investor directors have consent/voting rights and the non-investor directors do not, governance frameworks and mechanisms are in place to ensure all directors act in the best interest of the company (and not of the investor) to complement and comply with obligations under the Companies Act 2006.

Note: If the university were holding synthetic equity/ exit payment entitlements in lieu of common stock, as a non-shareholder the university may not hold a board seat in line with market practice. However, the rationale and benefits as to why universities hold equity and board seats are still relevant. Though, as also noted above, synthetic equity/exit payments are uncommon in the UK.

⁷ Board observer status for the university can sometimes offer a university staff member an opportunity to gain valuable board experience. However, it could also be perceived to allow the university to potentially influence board activities (e.g. as a shadow director). This can typically be managed through the usual conflicts of interest policies.

3.2.9 Transaction Fee, Legal Costs, Monitoring Fee

A fair approach to transaction fees is for each party to be responsible for their costs (with exception for the spin-out to pay the relevant reasonable out of pocket expenses in respect of each investor director, e.g. travel costs). This approach incentivises a swift transaction and keeps parties focused on progressing negotiations and being accountable for legal expenses. Parties could consider sharing counsel (existing and new shareholders) for cost efficiencies. The use of pre-agreed term sheet templates could further encourage cost efficiencies. It is usual for parties to be responsible for their own investment transaction costs.

An alternative to parties bearing their own costs (in relation to the investment transaction and ongoing monitoring) is for the spin-out to pay the investor's legal costs for external counsel. Where this arrangement is in place, then all parties using external counsel should receive the same benefit i.e. the university should also have their legal costs paid for by spin-out. Payment should be made at deal completion from the incoming investment, not in advance of deal closure.

Monitoring fees for early-stage companies are not usual, as it is preferable to have cash stay with the company and to minimise board expenses. An exception is venture capital trust funds who do typically charge arrangement and monitoring fees, given their own internal fee structure. Where a board payment is requested, ordinarily it is a nominal amount and/ or is to be a capped contribution by the spin-out (under £5k).

3.2.10 Term Sheet, Investment and Transaction Timeframes

It is typical for term sheets to include a commitment to timely completion. Committed timeframes may relate to reaching agreement on all terms within the term sheet, or for completion of the investment transaction etc., with 30-day or 60-day timeframes common. This has direct relevance for completion of the full deal itself, including timely execution of the HoT and licence agreement. Swift transaction times for deal completion are strongly encouraged to reduce the cost of transacting, with under three months a preferred target timeframe.

3.2.11 National Security and Investment Act 2021

The National Security & Investment Act 2021 came into force on 4th January 2022 and applies to companies operating in one of 17 specified sectors. It provides for mandatory notification regime for those companies where a third party takes ownership of more than 25% of the shares or voting rights. The Secretary of State can also 'call-in' and review transactions, prior or following completion, which could include asset (IP) licensing transactions. As such, parties should consider, at the outset of the spin-out process, whether a mandatory or voluntary notification should be made, either at the time of (i) the university taking an equity stake (if over 25% of the shares or voting rights, or if there is any concern around national security sensitivities), (ii) the venture capital investment being obtained, and/or (iii) the university licence being entered into.

The NSI Act can have a significant impact on a spin-out company, and it is recommended that expert legal advice is sought early about any implications.



3.3 Heads of Terms, HoT Licence Agreement

3.3.1 Royalties and Success-Based Milestones

University IP is core to the university's ability to form spin-out companies as a route for research translation and impact creation. Royalty and success milestones offer a method for financial return above that of equity realisation, noting the dilution effects of a university's shareholding over time.

Licensing fees demonstrate the ethos of parties sharing in value as it is created. Licence fees are typically a mix of royalties (e.g. on sales, use of process, manufacturing etc.) and lump sum payments (e.g. signing fee, annual fees, milestone payments etc.). Royalties and lump sum payments due are to be carved out from net receipts (sometimes not entirely synonymously referred to as non-royalty sub-licence income) to avoid 'double dipping' (see Sub-Licensing).

The Guide makes the following recommendations.

- To set licence fees using technology valuation appraisal methodologies alongside clear benchmarking and comparators, derived from internal and external sources, giving consideration to breadth and strength of IP, as well as the spin-out's business plan. Tools such as net present value (NPV) calculations should be employed to give confidence to transaction and benchmarking data sourced from reputable thirdparty sources to determine general licence fee parameters. Other methodologies such as 25% rule, 'cost-plus/return on costs' basis may also be employed to help benchmark. These parameters and comparators can be used to state the case and provide rationale for the net sales royalty rates and broader licence terms being proposed.
- To set licence fees appropriate to anticipated spin-out budget at a given time, in line with market rates. Recognise risk sharing profile across founders, investors, universities, (balanced with the anticipated share in some of the rewards). Licences with university spin-outs are different to those with multinational pharmaceutical companies, primarily owing to the less secure cashflow of spin-outs. While it is common and broadly supported that the spin-out will want to preserve early cashflow to develop technologies and grow the company, the university's desire for an early return to support their own cash position should also be considered. It is generally accepted that, starting with market rates, there is a skewing towards back-weighted licences (i.e., licence fees pushed back to later dates such that smaller payments

typically are due in the first years and larger payments are due in future years), balancing a university's need for early payment returns against an early-stage spin-out's budget. However, mechanisms such as deferred or partial payments (e.g. 90% milestone payment deferred until partnered/acquired) should be avoided⁹.

To consider the whole deal in totality, not just royalty rates, to facilitate productive negotiations. What terms across the HoT (licence) and the term sheet (spin-out formation) can be offset against each other to facilitate a win-win situation and reduce long negotiations and high transaction costs? E.g. are upfront, earlier certain payments more attractive than higher royalties that may never be realised? Are higher royalty rates more attractive than a larger starting equity shareholding, or any equity at all? For context, signing/upfront payments in licences to life sciences spin-outs are typically low (to help preserve immediate cashflow) and not in-line with signing/upfront payments seen in licences to big pharma, as this is compensated for with the university's equity stake in the spin-out. That is, an upfront lump-sum payment aims to 're-imburse' the licensor for expenses incurred to develop the IP to a stage where a licence is possible and signing is enabled, (e.g. R&D costs, administration costs, overhead costs, specific out-of-pocket commercialisation costs etc.). Universities will often take equity in the spin-out instead of receiving a high upfront signing fee to help preserve cashflow for the spin-out.

Milestones and royalty rates are negotiated by reference to fair market value. The paradigm is that IP is inherently unique and case-specific factors means no two licences will likely be (nor should be) the same. That said, both universities and VCs of the TenU member group acknowledge royalty rates for therapeutics organically tend to land within relatively tight parameters, in correlation to the development stage of the Licensed IP. Pre-agreed licence fee ranges within a HoT template can facilitate faster licence transactions.

⁹ While in the UK it is recommended avoid deferred payments, this is in contrast to USA-counterparts, where it can be more common for a university to defer up to as much as 90% of milestone payments until a partnering or exit event occurs, if requested, to further help the start-up preserve early cash.

Typical Considerations for a Heads of Terms



Focus should be on optimising an integrated deal, not on optimising individual items. The deal should be looked at in totality, with this guidance provided to support starting discussions and not as a template to drive negotiations. One item can influence other items and this can stretch across the licence fees and/or the HoT and Term Sheet.



Individual universities may have bespoke approaches to their licences and deal structures for their spin-out formations. For example, some universities may have minimal licence fees though request larger equity positions. Some universities may request smaller equity holdings and seek to realise value through payment of licence fees. Other universities may seek to strike a balance of shared value realisation through both the HoT and Term Sheet.



Spin-out companies need to preserve early cash flows and concentrate spend on progressing technology development. Licensors should avoid taking too much cash out of the spin-out at early stages and share risk with the spin-out. A share of the rewards should be expected when realised by the spin-out at later stages.



Fees will likely be different to fees seen in a big pharma licence. This is mostly owing to differences in cash flows. A spin-out company should also consider future collaborations and related transactions with key customers, including potential big pharma partners, when considering HoT (and term sheet) items.



All parties should aim to keep the deal as simple as possible to ensure faster transactions with fewer terms to negotiate. Protracted discussions increase the cost of transacting and may impact the throughput of spin-out formations within the ecosystem.



Technology Readiness Levels in the Life Sciences

Evaluation and Benchmarking Tools

Net present value (NPV) calculations (and/or other methodologies) can be applied as appropriate to the value of the deal. Risk adjusted NPVs (rNPV) are commonly used for life science evaluations, incorporating a risk adjusted discount rate across the anticipated lifetime of the licence. Risk adjusted discount rates used will depend on multiple factors, such as stage of technology, cost of capital, risk appetite, structure of deal and in several instances the university's policy. While typical ranges are commonly 15%-25% for risk adjusted discount rates, specific market circumstances may mean rates outside this range should be used. Generally, NPV calculations increase in certainty the further technologies progress along the TRL pathway.

Other methodologies may include income approaches (for example, the '25% rule' where 25% of the gross profit made by the product seller from sales before taxes somewhat represents a 'fair' royalty rate) and transactional approaches (for example 'cost-plus' calculations or return on R&D costs/return on market value calculations) to help set and substantiate proposed licence terms.

Reputable third-party providers, (e.g. ktMINE, RoyaltyRange etc.) are to be used to source benchmarking data and these data should be used to 'sense check' valuation models. Avoid cherry-picking only data points that support one argument. This can erode trust and is not meaningful.

Signing / Upfront Payment

Usually a signing/upfront payment from the company to the university is a nominal amount relative to the deal value, giving particular consideration to initial equity position of the university in the spin-out. For example, the payment may be at around £2,000 for early TRL and/or where university equity position might be larger, or low to mid-tens of thousands for later TRL technologies, where the university equity holding may be lower.

In some less common instances, the initial signing fee may be under £2,000, though this is compensated for in later stage payments.

Historical patent cost recovery may be added to the signing/upfront payment to appear as one item in the HoT, or alternatively can feature as a standalone item in the HoT.

Annual Fees / Maintenance

Usually annual fees/maintenance fees to be paid by the company to the university are nominal amounts relative to deal value. Annual fees encourage faster technology development by the spin-out while providing the university with a basic return. They may or may not be payable from the first anniversary of licence execution, may or may not start at a lower initial amount gradually increasing to a maximum over the years, and may or may not cease once product sales are achieved. Annual fees/maintenance can start at around £5,000 through to low to mid-tens of thousands, and in less common instances can be higher.

Developmental Milestones

The HoT may include any number and combination of development milestones. Typically, development milestones include lump sum licence fee payments in line with progress made through the regulatory pathway, for example at commencement of IND/Phase I/Phase II/Phase III studies, and gaining of marketing authorisation in particular territories (e.g. USA, EU/UK, APAC/ ROW etc.).

Generally, universities will share risk associated with technology development and will expect a share of the rewards once generated. Universities will often structure the licence to the spin-out such that it is 'back weighted', where more substantial licence fees are due to the university once value is realised and risk reduced, e.g. when the above milestones are reached. This approach helps to preserve the start-up's cashflow, however the need to balance this approach against the university's own cashflow is to also be recognised by the parties.

As such, lump-sum payments associated with development milestones are often a point of negotiation. To facilitate discussions, some recommended guidelines include:

- Early-stage development milestones (e.g. commencement of IND for an early TRL technology) can be in ranges between £25,000 and £50,000 or more if the university holds more equity, or between £75,000 and £125,000 or more if the university holds less equity;
- Later stage development milestones (e.g. commencement of Phase III studies for a more mature TRL technology) can be in ranges of £1 million to £2 million.

Royalty Rate on Net Sales

When negotiating an agreeable royalty rate on net sales, justifications for proposed rates are likely to be important for moving negotiations forward. Royalty ranges were comprehensively discussed amongst contributors to this guide and it is to be re-emphasised that terms, including royalty rates on net sales, are to be considered in the context of the whole deal, with consideration to other terms within both the HoT (for example, net receipts percentages, sales milestone payments etc.) and term sheet (for example, smaller university equity holdings may attract higher licence fees and vice versa – and in some instances a university may not request any royalties on net sales, or other milestone payments, in exchange for much higher equity holdings).

It is recommended that each deal, technology and situation is considered and discussed in good faith to arrive at an agreed net sales royalty rate. Some suggested guidelines have been included to facilitate negotiations:

- For very early TRL technologies (e.g. know-how only IP estates, technology in low growth fields), there is broad support for typical royalty rates in the range of 0.5 and below 2%.
- For technologies more progressed in TRL, net sales royalty rate ranges are higher, with the range generally between 2 and 5%. This range is typical for many technologies.
- For later stage TRL technologies, for example technologies at clinical stage, those with stronger IP positions (e.g. multiple patent families, novel and unique IP estates) and those technologies with application in advanced, high growth fields and/or new modalities (e.g. advanced therapy medicinal products at late stage preclinical or clinical stages), royalty rates are typically above 5%.

Royalty rates on net sales are often tiered to recognise increasing value realisation, when individual product sales reach a threshold. For example, royalty rates on net sales up to product sales of £500m might be at X'%, whereas the royalty rate on net sales for product sales over £500m might be at X+0.5%. The increase in royalty rate on net sales at product sales over a threshold is usually between 0.5% - 1.5%.

Royalty stacking and combination product clauses are market practice for the life sciences sector. In the case that university-derived IP is stacked with licensee-developed IP or third party-derived IP, or a licensed product is bundled, there may be an apportion of relative contribution. The university may include a floor below which the university's share cannot fall (i.e. maximum floors for net sales royalty rates for stacked and/or bundled IP, e.g. maximum 50% reduction (or less) or a defined absolute royalty rate below which it cannot fall). A mechanism for dispute resolution is also recommended here to resolve potential disagreement. Note: It is usual for net sales royalty rates to be payable irrespective if licensee or sub-licensee sells licensed product. Please see 'Sub-Licensing'.

In certain circumstances. for example, where the type of technology or where unclear detail of spin-out's business plan at formation make it unworkable for net sales royalty rates to apply to sub-licensee sales, an alternative approach may be applied that recognises the sub-licensee's sales as net receipts. In these situations, a higher net receipts percentage would be negotiated by the university with the spin-out. **Sales Milestones**

The HoT may include sales-based milestones when sales are achieved by the spin-out, as an additional way for the university to share in value creation above the royalty rates on net sales. Generally, at this stage the value realisation and income generation is shared proportionately amongst those parties bearing early risk of the technology development, particularly where licence structures have been back weighted and development milestones minimised. Sales milestones can also be used as a way to better balance licence value when other licence fees may be lower.

Milestone payments on increasing sales volumes achieved (typically expressed as a lump sum payment due upon product sales reaching specific successive thresholds) can be applied in any number and combination of sales.

Typically the value of the lump sum payment due upon product sales reaching a certain threshold is anywhere between 0.5 and over 3% of the product sales threshold.

Royalty Rate on Net Receipts / Non-Royalty Sub-Licensing Income (NRSI)

Royalty rates on net receipts are generally tiered, decreasing as the technology is developed and moves along the TRL pathway, e.g. within initial 12 months of licence execution, pre-Phase I, pre-Phase II, pre-Phase III and post Phase III etc., (or may alternatively be based on time-based inflection points).

In the early phases of the licence and undertaking of technology development by the spin-out, there can be a balance between allowing the spin-out to sub-licence to generate a revenue stream for investment back in the technology and discouraging the spin-out from merely acting as an agent for sub-licensing without investing in the technology. As with other licence fees, consideration also needs to be given to other terms in the HoT and/or term sheet. Consequently, ranges for royalty rates on net receipts can vary.

As a general guide:

- Royalty rates on net receipts during the first phase (e.g. for the 12 month proceeding the licence execution) are ordinarily at the highest tier, noting that within this initial phase some universities may be more supportive of the spin-out sub-licensing the technology to a third party than others and as such, may have lower initial net receipts royalty rate than others.
- Royalty rates on net receipts post Phase III and beyond are generally at the lowest tier, as by this stage it is recognised the spin-out has made material investment into the technology's development and should be proportionately rewarded from sub-licensing activity.

Some universities apply a flat net receipts royalty rate (i.e. do not take a tiered approach), with the same percentage applying regardless of the period in which the sub-licensing activity occurs, though this flat rate approach is less common in the UK.

Note: Amounts due already from net sales royalty rate, milestone payments etc. under a head licence are to be excluded from amounts due from royalty rate on net receipts under a sub-licence. Please see 'Sub-licensing'.

Pre-agreed licence fee ranges within a HoT template can facilitate faster licence transactions.

3.3.2 Windfall Success

Windfall success payments are payments made by the spin-out to the university upon the spin-out achieving company valuation-based milestones. They may also be known as success fees, deferred payment(s) or similar and can be a way to bridge the gap on reduced licensing fees, sub-licensing fees and/or reduced equity allocations for the university. Payments may be one-off or a series of escalating payments (for example, linked to valuation triggers). (Note: being based on company valuations, these windfall success payments differ to sales-based milestones triggered by reaching certain sequential sales thresholds and it is common that a spin-out licence would include one or the other, but not ordinarily both).

Windfall success payments are an option that can be used as part of an integrated approach to achieve a net financial position. They may be used to pro-rata the total deal compensation for the university through payments during operations and/or payments at exit. In this sense, windfall success payments are a form of synthetic equity and should be considered in relation to other terms in the term sheet (including founding equity) and/ or licence HoT. See 3.2.1 University Equity).

An example guiding range for windfall success payment is between 0.5 and 5% of the spin-out company valuation at a relevant point in time (i.e. valuebased milestone or liquidity event). Windfall success payments should not cause illiquidity to the spin-out.

The possible use of windfall success payments should be considered on a case-by-case basis. Both advantages and disadvantages have been cited with adopting the use of windfall success payments.

Advantages

- Ability to simplify licence HoT negotiations, simplify term sheets and cap tables and transact swiftly by using windfall success payments in lieu of royalty payment obligations, i.e. negotiating only a payment for spin-out company's particular valuation or exit and avoiding the need to negotiate terms for receiving royalties for the duration of the licence. In this application, a wholly windfall success payment-based licence may be implemented as an alternative to conventional licensing structures and can be considered a form of synthetic equity (see 3.2.1 University Equity)
- A useful clause to breakthrough impasses that may be reached when negotiating equity shareholdings or royalty rates.

- Difficult to negotiate and problem-solve for multiple complex future events, including IPO valuations, termination of licence (risk windfall success payment 'disappearing'), a spin-out not reaching trigger valuation or exiting etc..
- Difficult to draft effectively to define what contribution the IP has to the final marketed product. For example, if a spin-out reaches a windfall success payment trigger based on company valuation in the short term, the payment can be more readily defined and justified than if the valuation trigger is reached in a far future point where the company's reliance on the originating IP can be questionable.
- Difficulty in implementing series of escalating windfall success payments through funding rounds, as it may be challenging to gain buy-in from spin-out as funding round milestones will need to be achieved on less, for example, the spin-out will need to achieve on £9.5m plus £500k windfall payment for what should have been achieved on £10m.
- It is not usual for windfall success payments to be included in conventional licences or term sheets. There may be, however, specific situations where windfall success payments could be used, for example, to help break through stalled negotiations. When used, they should be considered in the context of, and complementary to, the overall licence/ spin-out terms and conditions rather than an opportunity to 'double dip'.
- In most circumstances, equivalent outcomes can often be achieved, through larger milestones, larger annual payments or similar and the need for negotiating a future windfall success payment can be avoided.

3.3.3 Other Products (Enabled Products), Licensed Know-How and Technical Information

Know-how can be a critical component of the overall IP estate and can be a licensable asset that attracts licensing fees. This clause acknowledges that a university's contribution to enabling product development goes beyond licensed patents. The specific know-how will need to be assessed on a case-by-case basis and will need to consider the spin-out's circumstances, the intended business plan and ongoing active involvement between the spin-out and the university when scoping and defining know-how and establishing know-how related terms.

When licensing know-how, it is recommended that the know-how items be clearly defined. List and/or show relevant know-how that the enabled product/other product may rely on in the IP licence agreement. This will also greatly assist the university's due diligence activities on the IP, (which can be very challenging when know-how is not clearly defined), speeding up the licence transaction.

The spin-out needs sufficiency of IP for the company to operate (and if the spin-out is accessing know-how on an unauthorised basis, it could well be picked up in due diligence in future rounds). It is in the interests of the university to clearly define know-how elements and make them available to the spin-out as part of the licensed IP.

It is also recommended to clearly define 'enabled product/other product'. In some cases, this definition will include products which do not embody licensed know-how, or whose manufacture does not make use of licensed know-how, but whose development used know-how (i.e. as a stepping stone). It is recommended that the Parties discuss the extent to which this is appropriate.

When determining appropriate licence fees, consider the nature of the know-how items (e.g. technical information, specific experimental results, data sets, materials, trade secrets, papers, software codes etc.), how they have aided product development and value creation (complementing patent utility, fast-tracking or spring-boarding development timelines, supporting regulatory filings etc.), whether they have narrow or broad utility across single or multiple development projects (e.g. platform technologies) etc.. The university should aim to balance the value of know-how against other registered IP items of the licensed IP and be pragmatic about the level of licence fee the know-how can justifiably attract.
Generally, lower licence fees are applied to licensed know-how when compared to licensed registered IP. It is recommended royalty rates for know-how-only licences be kept small and realistic (which will also be less likely to be subject to challenge). This reflects that know-how is a more fragile barrier to entry than a patent and is not a true monopoly right). Commonly, a 50% drop down from the head royalty rate is applied when relying on licensed know-how only in relation to post-patent IP. Where the licence has always only been for know-how-based IP (i.e. non-registerable IP), the licence fees may be lower again. See Royalties and Success-Based Milestones.

Debate exists on know-how items that become non-confidential during the term of the licence and the appropriate licence fees that should apply, if any. A difference of opinion exists between universities ('small % should apply') and investors ('0% should apply'), with both agreeing to reserve the topic for case-by-case negotiations.

When determining an appropriate royalty rate for non-confidential knowhow items, consideration should be given to factors such as unique competitive advantages conferred, first-mover benefits for the spin-out, difficulty of competitors reducing IP to practice even if in public domain (e.g. methods for reducing to practice may be proprietary and difficult to replicate) etc.. One approach to managing this could be that the university and investor agree the initial 50% drop down from head royalty rate for confidential know-how, and a further 50% drop at some future point after the confidential know-how enters the public domain. The triggers for this need to be well defined, though could simply be time-based.

Alternatively, the spin-out can choose not to take a licence to the know-how and wait for the know-how to enter the public domain.

If access to academic(s) is required to assist with reducing IP to practice and effective transfer of IP, the academic's involvement should be time limited. The duration will be dependent on the know-how/IP type and complexity of opportunity, however a time limitation of two days is common. If longer is required or ongoing academic involvement is expected, consider a separate consultancy agreement.

3.3.4 Licensing Improvements

Universities and investors recognise the benefits to both parties of direct improvements of licensed IP created at the university being made available to the spin-out. The spin-out wants access to improvements to ensure the technology it has taken a licence to is not superseded by the research group. The university can maximise the impact of the originally licensed IP along with the new improvements.

It is recommended the university offers the spin-out a licence to narrowly defined university-generated improvements of university IP for a period of time, where feasible¹⁰. Improvements are considered to:

- have non-severable relationship to initially-licensed IP (e.g. only if practice of the improvements would infringe upon a claim within the initially-licensed IP);
- be associated to principal investigator/inventors of initially-licensed IP;
- arise for a limited period following commencement of the spin-out licence (two years is common, though can be flexible), or while a sponsored research agreement from spin-out to university is in place; and/or
- have no or manageable encumbrances (university needs to be sure it can make IP rights to improvements available to the spin-out).

Defining improvements and providing time-bound access will help optimise the benefits-and-pitfalls balance for making improvements available to the spin-out.

One approach for licensing the defined improvements to the spin-out is for the universities to automatically include in the existing licence agreement a provision for the spin-out to access the defined improvements, on terms to be agreed. These may or may not be the same terms as in the existing licence (as below).

¹⁰ The common approach in the UK of offering access to improvements for the spin-out as part of the licence (either directly incorporated or by separate agreement) is in contrast to the approach in the USA, where it is uncommon to include improvements. Some USA universities will agree to include improvements sometimes, though not always and many USA universities don't at all.

An alternative approach is for the university to give the spin-out a first option to license such improvements and have improvements subject of a separate agreement (outside of the existing licence). This approach is used when potential pitfalls could exist by automatically bringing improvements to licensed IP into the licence that have not yet been made or disclosed, or are not actually supported by the spin-out. Such pitfalls can include:

- encumbering the research group's outputs with terms in conflict with the original funder terms;
- pre-committing and encumbering the research group's outputs without due reward / establishing a pseudo 'pipeline agreement';
- biasing outcome reports from researchers' university programmes to entice new licensing/equity opportunities.
- perceived restriction of academic freedom, (researchers working as a pseudo-contract research organisation (CRO) for the spin-out);
- precluding ability of research group members to participate in certain external funding bids (e.g. if outputs are already pre-encumbered); or
- bringing in new, future inventors into the spin-out who were not considered at the initial negotiations (this may be addressed by ensuring a mechanism is in place to suitably reward incoming inventors either through sharing of unallocated equity, licence fees or other).

While improvements may end up being licensed on the same terms as the existing licence, the university will often reserve the right to licence improvements on terms to be agreed. It is difficult for a party to fairly prenegotiate terms and have the university commit to a grant of rights to improvements which are yet created and defined¹¹.

If the access terms for the spin-out are too narrow, the spin-out can alternatively consider funding specific research at the university.

The university will likely reserve rights to continue to use the universityderived improvements for training and educational purposes (see 'Reservation of Rights' below).

Where the spin-out creates the improvement, the improvement is generally owned by the spin-out. There are instances where the university may request access to spin-out-derived improvements for training and educational purposes. This should be addressed on a case-by-case basis, though generally, the spin-out should consider the following.

- The type of improvement IP i.e. if the improvement is not a patent but confidential information, is the spin-out willing to offer this to the university?
- Licence fees target symmetry, i.e. should licence fees to the university be adjusted downward if the spin-out grants a licence to the university under its improvements for training and educational purposes?
- **Timing** whether training and education rights to spin-out derived improvements could instead be given to the university only if the licence is terminated or otherwise comes to an end.

¹¹ One exception could be where the licensed patents definitions in the existing licence includes divisionals, continuations, extensions etc, improvements within the limits of the licensed patents definition will be made available on existing licence terms, (e.g. spin-out company can have patent improvements on existing terms though not new patents/technologies).

3.3.5 Field of Use, Diligence Clauses, Minimum Royalties, Annual Payments, Mandatory Sub-Licensing

It can be challenging to optimally balance a spin-out's desire to gain the broadest possible licence in terms of field of use and territories, with the university's ambition to maximise the impact (societal, economic, global) of its licensed IP within a reasonable timeframe (by the spin-out or otherwise). It is important to support the spin-out and set it up for success and for the university to grant rights to the spin-out to deliver its business plan.

Incentives to encourage full exploitation of IP rights by spin-outs, while providing university with fair returns, are commonly included in the licence, (e.g. diligence conditions, annual payments, minimum royalties etc.). Reversion of IP rights from spin-out to university, including the ability to terminate the licence, should diligence conditions not be met by the spinout are included to preserve the opportunity for the university to maximise impact from the IP if the spin-out cannot do so. However, best practice is to first provide appropriate grant of rights relative to the proposed business plan commencement.

Carefully consider the scope of grant of rights upfront to optimise licensing efficiency, strengthen spin-out/university working relationship and minimise risk for disputes. Grant sufficiently broad IP rights to the spin-out to maximise commercial potential.

Some common approaches to achieve the right balance of the rights granted to the spin-out over the longer term include:

- Diligence milestones: These are performance milestones to be achieved by the spin-out over a period of time to retain licence rights (for fields of use, territories, or to the licence overall). Diligence milestones may be based on investment, efforts applied, and/or outcomes.
- Escalating annual maintenance fees: such fees incentivise the spin-out to progress development activities swiftly. Alternative approaches to annual maintenance fees are minimum annual royalties or reduced annual fees upon release of unused IP, although this latter approach is rarely seen in the UK.
- Adequate reversion rights for university: If a spin-out is unable to meet diligence conditions as set out in the licence, the university can retain the right to have IP returned (for example, returning certain fields of use/

territories, licence termination etc.). Reversion of rights can be particularly important for platform technologies and those technologies with more than one application. In setting reversion rights, consider the following before of licence termination:

- → Appropriate precursor steps for missed diligence milestones e.g. time extensions, monetary payments, expert determination etc.
- → The process and mechanism for a remedial plan, including allowing the spin-out sufficient time to enact remedial plan.
- → Time-bound exclusivity. Offering exclusivity limited to a future point in time, at which point the licence converts to non-exclusivity. In practice this option may be challenging to successfully exploit and manage long term.
- → A provision for mandatory sub-licensing by the spin-out. Mandatory sub-licensing is an outlier and very seldom used. If included, it needs to be carefully considered.

An alternative approach is for the university to grant more narrow rights upfront and expand the scope of rights as diligence milestones are met. Below are a few examples.

- Initially grant rights to select fields of use only and include milestonepredicated and/or time-based options to add fields of use as the spinout builds capacity to pursue them.
- Grant co-exclusive¹² or non-exclusive rights initially to the spin-out (that is, the ability for the university to grant licences to more than one licensee), with conversion to exclusivity once certain diligence conditions have been met. This approach is not commonly used in the UK. While there are certain circumstances in which a co-exclusive or non-exclusive licence approach is acceptable, generally a spin-out without exclusivity may find it challenging to raise external funding.
- Ahead of moving to licence IP on a co-exclusive or a non-exclusive basis, the university should consider how the IP will be managed. For example, if a patent is being exclusively licensed to Party 1 and also being exclusively licensed to Party 2, there is potential to face issues around enforceability. If Party 1 wants to enforce that patent, the action can risk invalidating patents for others. Co-exclusive licensing often increases the complexity of negotiating the spin-out licence and can significantly increase time taken for the spin-out formation and the associated legal costs of all parties (as it often turns into a three-way, or multiparty, negotiation).

¹² Co-exclusive is used more so in US practice and not often in the UK. Its meaning can be deemed unclear. It many cases, it just means a sole licence (i.e. both the licensor and the licensee are able to use the IP in the same field of use, but the licensor promises not to grant any licences to other third parties). For example, in a US-style pharma co-promotion agreement, coexclusive IP licences are often granted. It may be more commonly referred to as 'field of use licensing' in the UK.

With such approaches, licence terms and fees may need to be negotiated, either upfront or as the licence progresses. This can be onerous for the spin-out as it provides no certainty, and may be quite burdensome to implement. It can also be challenging to effectively implement these alternative approaches where control of patent maintenance, prosecution and overall strategy is passed from the university to the spin-out at time of licence execution (see section 3.3.7 Patent expense reimbursement & patent prosecution). Reversion rights, dropped territories and other considerations can make field retractions/ expansions impractical to manage for the licensor.

Granting appropriate IP rights are very much linked to the financial terms of the term sheet and licence HoT. IP rights favourable to the spin-out should have appropriate licence fees for the university, and vice versa.

For exclusively licenced IP, IP ownership as part of a licence/sub-licence is determined on case-by-case basis (Note: university may have IP ownership policy). In practice, resolving IP ownership often centres on control of IP prosecution.

Transfer of control for IP management and prosecution from the university to the spin-out, rather than transfer of IP ownership, is often agreeable for both universities and spin-out, though negotiation on this point will likely be on a case-by-case basis. It is generally accepted the spin-out needs autonomy to direct IP prosecution, as it will often be developing its own IP and needs to guide overall IP strategy. Often, where the university permits the spin-out to lead IP prosecution (directly or via university), the university can readily retain IP ownership. That is, if the university retains ownership of IP, it often delegates some or all of IP prosecution to the spin-out, (often with university approval rights), including IP strategy and costs (see section 3.3.7).

Universities will need to determine their appetite for future assignment of IP to spin-outs, for example, once a specific value inflection point is reached or period of time has passed. Individual universities will have differing views on eventual transfer of IP ownership, as will investors.

Possible assignment of IP from the university to the spin-out may have impact on aspects of the spin-out term sheet and/or licence HoT. Where it is contemplated that IP ownership might be assigned from the university to the spin-out at a future point, the university should consider at the time of negotiating the HoT what impact a call for assignment might have on the licence fees and how, at the time of assignment, the licence fees terms might be balanced, preserved or bought out. The stage at which assignment is to occur should be clearly defined upfront (e.g. after achievement of certain milestones, upon patent issuance and not before, at time of IPO, after first sale of product, after X number of years etc.). For example, a university assigning IP ownership may bring about higher equity shareholdings for the university, or may drive higher licence fees recognising the licence will likely be of shorter duration (assuming a termination of future royalty obligations on the assignment). A university may want to consider requiring the future royalty stream to be bought-out on an IP assignment, rather than simply terminating. However, this may be difficult to agree commercially (as the lump-sum amount involved may be unaffordable for the spin-out), and difficult to value in the event of an IP assignment. In this situation, it is advisable for the university to include a provision in the HoT that a third party may be brought in to value the future non-fixed payment components of any deal (e.g. royalties etc.) to ensure a fair valuation. Or there may be no change to payment terms, and an agreement that the spin-out company will continue payment provisions (e.g. royalty-like payments) post assignment. This would be characterised as deferred consideration for the IP assignment and would be contractbased, as opposed to licence-based. Note: it may be challenging and costly to pursue damages and enforce payment of deferred consideration when the licensee defaults via a contractual breach rather than simply having ability to terminate a licence when licence fees aren't paid, (this puts the licensee under real pressure both to pay any royalty arrears and bring itself into compliance for the future). Once assignment occurs, it may also become difficult to regain ownership by the university of the assigned IP (including in the event of spin-out insolvency). Both scenarios may be exacerbated when the licensee further assigns the assigned IP. This is one reason some universities do not offer IP assignment to spin-outs.

3.3.6 Sub-Licensing

Universities generally support a spin-out's ability to sub-licence. It is usual for the university to want controls in place to minimise risk and maximise impact potential of IP exploitation. This needs to be balanced with a spin-out's desire for flexibility when sub-licensing its exclusively-licensed IP with minimal university-imposed restrictions.

When sub-licensing is anticipated within the spin-out's business plan, it is important the university considers the breadth of IP rights to be granted, and the spin-out's ability to deliver its business plan, including sub-licensing likelihood and scope of sub-licensing potential. There should be confidence that suitable mechanisms exist in the licence to ensure market demand can be met.

Often sub-licensing opportunities come about because a spin-out has broad fields of use that aren't initially required, typically due to the lack of cashflow to pursue multiple product developments early on. It is recognised sub-licensing offers a spin-out technology development efficiencies and a source of financial income to support the spin-out's core operations. However, the spin-out's ability to sub-licence needs to be balanced with incentivising the spin-out to invest and progress technology readiness level itself and not simply becoming a sub-licensing agent. This 'asset flipping' is discouraged as it increases product development costs and timelines.

Common practice for sub-licensing provisions to include the following.

- Requirement for spin-out to notify the university of a sub-licence prior to execution, including allowing the university to know the identity of the sub-licensing entity. This may include seeing the financial details of the proposed sub-licence, although the head licence may be structured such that seeing financial detail isn't required ahead of the sub-licence being entered into. This often becomes known as part of auditing in any case.
- Terms regarding when a university may prohibit a spin-out from sublicensing to or working with, directly or indirectly, proscribed entities. The university will often have specific definitions or lists of proscribed entities.
- Sub-licensees being bound by key terms and definitions in line with head licence.
- Having net sales royalty rates, milestones and other licence fees outlined in the head licence due and payable to the university regardless of whether the licensee or sub-licensee achieves. Flow through of licence fees such as net sales royalties and milestones to sub-licensees is standard. (There may be certain circumstances where it is unworkable to flow through net sales royalties and milestones to sub-licensees, for example, for particular technology types or where the spin-out's business plan is unclear at time of formation. An alternative position could be to recognise such income

as net receipts and for the university to negotiate higher net receipt percentages to counter-balance the reduced income potential from net sales royalty rate).

- Receiving net receipts income generated by sub-licensees (note: the university will prefer net receipts on monies 'due', not 'received' as this moves credit risk and bad-debt from the university to the spin-out, who has contracted the sub-licensee). Net receipts are a percentage of all other amounts due from sub-licensee to licensee (cash or otherwise). For clarity, direct net sales royalties and milestone payments due under the head licence should be carved out from net receipts such that the university is not paid absolute amounts twice for the same event and avoids double dipping, i.e. the net receipts percentage should apply to balance only.
- Having decreasing net receipts percentage rates over time, or as value infection points are reached, to reward the spin-out for technology development and avoid technology flipping (see 'Royalty Rate on Net Receipts / Non-Royalty Sub-Licensing Income (NSRI)' in 'Royalties and Success-Based Milestones'). The timings and triggers for net receipts percentage reductions are commonly linked to technology development milestones in the business plan (e.g. First patient dosed in Phase I attracts a higher net receipts percentage than First patient dosed in Phase II etc.). Net receipts percentages should relate to size of investment and should be sensible and manageable. They should also be applied and calculated based on when the sub-licence is executed, not when the revenue is received to avoid gaming the revenue recognition to select a lower net receipts percentage;
- Research income being excluded from net receipts, (this is to be accounted for as R&D). However, if R&D monies received exceeds actual R&D spend, then the balance is to be considered and treated as net receipts;
- The number of permitted of sub-licensing tiers is a point of negotiation. Universities may want sight of sub-licensing activities and will allow one tier of sub-licensing in the first instance with the spin-out needing to consult with the university to be permitted additional tiers. (Note: the spin-out's ability to sub-licence to contractors, suppliers and other entities providing services relating to the development or manufacture of a licensed product are usually excluded from the one-tier permitted limit as the spin-out needs to be enabled to sell the product and needs freedom to sub-license in these circumstances). Spin-outs may want broader sub-licensing

Note: the start-up's ability to sub-licence to contractors, suppliers and other entities providing services relating to the development or manufacture of a Licensed Product are usually excluded from the 1-tier permitted limit as the startup needs to be enabled to sell the product and needs freedom to sub-license in these circumstances

3.3.6

freedom and seek unlimited sub-licensing tiers to ensure sub-licensing freedom for potential future sub-licensee partnerships. As such, sublicensing tiers will likely be negotiated on a case-by-case basis with the most appropriate level of sub-licensing limitation, if any, being dependent on the current and foreseeable contracting parties.

What happens to the sub-licence when the head licence terminates can vary and be dependent on how / why the head licence terminated (e.g. mutual convenience, licensee breach, licensee liquidated, etc.), and who the sub-licensee is (e.g. proscribed entity). These factors will be important when the university contemplates taking on the sublicensee as the new licensee, (i.e. financial and reputational risks). Some universities prefer that the sub-license immediately terminates upon termination of the head licence to mitigate risk. Others support the university automatically continuing on the sub-licence and the sublicensee stepping into the shoes of the licensee taking on the head licence under the same terms and conditions, save for (i) the payment terms (the sub-licensee should not get a windfall benefit if the payment terms in the head-licence are less than in the sub-licence; and (ii) field of use (the sub-licensee should not benefit from the field of use in the head-licence, where the sub-licence covered a more limited field of use). Here it is deemed in the interests of both the university and spinout/sub-licensee (suggesting if the terms of the head licence aren't abided by, it will be void anyway). Others are somewhere in between and allow for a short negotiation period, e.g. three months, where the sub-licensee can negotiate with university to step into the position of the (previous) licensee as part of the head licence (during which time only the sub-licence may continue while negotiations are underway). Here it will be important for the licensor to ensure no additional obligations will be consequential of the sub-licensee continuing on as the licensee.

Often the spin-out will consider its ability to sub-licence as impacting its ability to operate. There are examples of universities allowing the sublicensee to take on the head licence in the event the original head licence is terminated. Not allowing some automatic or negotiated termination can risk the head licence not being agreed to in the first instance (as a potential sub-licensee wouldn't sign a sub-licence that was at risk of being terminated through no fault of its own). When licensing, it is recommended the university retain reversion rights, such that where the spin-out (including via any sub-licensee) no longer can/wants to exploit IP (e.g. based on non-achievement of milestones etc.), IP rights for commercial purposes revert back to the university (in addition to the university's ongoing IP rights for R&D and teaching purposes).

As noted above, it is likely easier to enforce compliance with licence terms if there is an existing licence, (i.e. IP not assigned) contributing to the strong preference many universities have for not assigning IP and instead delegating IP control to the spin-out. If IP is assigned, while there will likely be a contractual arrangement in place, it may be much harder for the university to manage compliance.

A university may determine, however, the negative impact of not including reversion rights may be minimal in the instance the licence has not worked out. If the IP assets have value in the market, they would be sold on to another company, as reversion back to the university doesn't necessarily place the university in better standing to out-licence again. If the university contemplates not including reversion rights in the licence, it is recommended the inventors and founders are consulted to ensure this position is supported to avoid potential future disputes.

3.3.7 Patent Expense Reimbursement and Patent Prosecution

Patent expenses incurred by the university up to the point of licensing are commonly reimbursed by the spin-out in consideration for IP rights to be granted. This may be a separate patent reimbursement term or rolled up as part of a signing fee.

Thereafter, the spin-out typically pays ongoing patent expenses.

To help preserve spin-out cashflow, the university may consider spreading larger patent expense reimbursements over a period of time, e.g. 50% due at signing of licence, 50% due at year one anniversary.

While some universities may prefer to keep control of prosecution, for exclusively licensed IP it is generally commonplace that the university allows the spin-out to manage ongoing prosecution following IP licence execution, noting an agreed minimum list of jurisdictions. Where jointly developed patents between the university and the spin-out subsequently arise, the university IP rights are often licensed to the spin-out and the patents managed by the spin-out (with approval rights for the university).

Note: From 1 June 2023, when the Unified Patent Court and Unitary Patent start operating, the university and spin-out will need to determine responsibility for decision making on control of (i) seeking unitary effect for a European patent; (ii) opting the licensed patents out of the UPC (and withdrawing any opt-out).

Where control of prosecution is by the spin-out, the HoT ordinarily includes a provision that allows for the university to take on any IP rights (field, territories etc.) abandoned by the spin-out.

For non-exclusively licensed IP or field/territory-restricted (e.g. co-licensed) IP, it is more normal for the university to retain control of prosecution (and continue to bear the costs of prosecution) and consult the licensee as to prosecution activity. Alternatively, the parties may prefer to share prosecution and costs across those licences.

In each scenario, in the event of any threatened or potential infringement of the university's IP, it is important the licence agreement include terms which clearly specify which party shall have control over the enforcement proceedings, whether the other party is obliged to provide reasonable assistance in enforcement actions and how costs and any damages awarded in the enforcement actions may be shared between the university and the spin-out.

3.3.8 Reservation of Rights

Teaching, training, research and development are the university's core activities and the spin-out/investors usually agree to the university reserving such rights when exclusively licensing IP for commercial purposes. Any restrictions placed on these activities may otherwise impact academic freedom and potentially place the university in a disadvantage to that of its peers who enjoy full academic freedom.

For full reservation of rights for the university, it is recommended that:

- The university have a perpetual, worldwide, royalty-free license to carry out academic research and teaching; and
- No rights are granted to the licensee under IP other than the expressly licensed rights.

Best practice for university reserved rights beyond this level is debated, in particular with regards to the following.

i) University reserved right for academic research and teaching to include clinical research

The university reserving the right to undertake clinical studies (e.g. Phase I), using IP licensed to a spin-out can be contentious. Such university-led clinical research, resulting in 'unfavourable' outcomes may have perceived detriment to spin-out's R&D activities and overall technology/company valuation (particularly if the university negotiated rights to spin-out's improvements (see 'Licensing Improvements') and the unfavourable clinical results are consequential of research being undertaken by university on those improvements). The unfavourable outcome may not be related to the technology (e.g. poor study design) but can nevertheless have significant negative effect on the spin-out.

From the university's perspective, it is important its academics and researchers have the ability to continue their academic endeavour (with an active commercial licence in place) and in particular, not hinder the research scope of those academics and researchers not involved in the licence. Further, universities have a vast number of academics and researchers at any given time and it is extremely challenging for a TTO to practically monitor all ongoing research activities to prevent such research being undertaken. While an agreed framework approach for this item continues to be discussed, some emerging recommendations may include the following.

- Have the university seek approval from the spin-out prior to commencing clinical studies. For reasons mentioned above, the practicality of this may be challenging, though where universities have a central Human Research Ethics Committee (HREC) from which most internal clinical studies are reviewed, the approach may be more feasible.
- The spin-out could limit restriction of undertaking clinical research to academic founders only (those involved in the spin-out), noting those other academics at an arms-length cannot be restricted. This approach acknowledges the academic founders have chosen to exploit research through a spin-out company and actively influenced their own 'academic freedom'.
- The spin-out and university could plan for clinical trials in consultation and undertake them in collaboration. This approach does not require approval routes and is considered the preferred approach.
- ii) University reserved right for academic research and teaching to include the ability to accept research sponsorship from a commercial third party.

A university's ability to accept industry funding from a third party (i.e. not the spin-out) similarly aims to protect academic freedom. It allows the university to compete with its peers for industry funding for all research proposals (where permitted), i.e. if the research can be undertaken with any university, the licensing university should not be prohibited from bidding for that research.

There may be circumstances where having the university undertake sponsored research with a third party may be beneficial for the licensee's development programme. This will likely require tripartite discussions between the university, licensee and third party to help set the proposed research up for success.

The university will need to be cautious undertaking sponsored research involving improvements with a third party who is not the licensee. The third party may subsequently file a patent application on improvements. Even if the third party would be unable to exploit those improvements commercially, to the extent that they were non-severable and dependent on the licensed IP, the third party could still file the patent application and block the legitimate spin-out's freedom to operate. The spin-out may then need a cross-licence with the third party to continue.

Where the sponsored third party research is not undertaken in consultation/collaboration with the licensee, the university would need to be confident it could defend 'legitimate research purposes'. The university and third-party-proposed research would need to fall within the research-use argument and be justified. There are instances where such purposes are based on legal foundation, e.g. UK/EU's research exemptions, USA's Hatch-Waxman Act etc.. However, there are many instances where it may be difficult to demonstrate research exemption or safe harbour exemption when undertaking third-party-sponsored research involving experimentation on licensed IP.

Although an agreed approach for this reserved right has not been reached, it is recognised there are both potential benefits and disadvantages to a university undertaking industry sponsored research with a third party who is not the licensee and it is suggested clear processes would need to be in place between the university and spin-out as to how such research would be undertaken.

Reservation of rights will often be a matter of university policy. It may be difficult for the university at TTO level to agree an alternative negotiated position.

3.3.9 Indemnities – as Related to Licence

Indemnities, warranties and liabilities are inter-related and should be considered with respect to each other.

Indemnification of a university (and its TTO and, possibly, other Affiliates and representatives) by the spin-out against losses, damages, claims or expenses suffered or incurred by the university resulting from any third party claim against the university arising out of or in connection with:

- The use by the spin-out of the licensed IP; and
- The development, manufacture or sale of, or other dealing in, the licensed products by the spin-out, or any end user (including claims based on product liability laws);

are generally accepted, as the spin-out's operations are outside of the university's control.

In some cases, the indemnity will extend expressly to losses arising from a breach by the spin-out of any applicable laws or regulations (including the Bribery Act), though this is less common.

An exception may apply in relation to such losses, damages, claims or expenses to the extent that they arise from, or are increased by, the university's negligence, or wilful breach of the licence or other wilful default. The spin-out will typically wish to carve these out from the indemnity. This tends to be subject to negotiation on a case-by-case basis.

3.3.10 Warranties

Indemnities, warranties and liabilities are inter-related and should be considered with respect to each other.

Universities will ordinarily be resistant to providing anything other than basic, minimal warranties as they are charitable, risk-averse organisations. Although universities commercialise technologies, they are not commercial entities. The spin-out may wish to take out insurance instead.

As a minimum, the university will usually offer warranties that: (i) it is duly incorporated and validly exists under the laws of the jurisdiction in which it is incorporated, and (ii) it has full power to enter into, and to perform its obligations and exercise its rights under, the spin-out licence. The spin-out usually requests in addition a warranty to ensure the university owns the IP and/or has right to commercialise, to give confidence regarding the chain of title for licensed patents. Generally, this warranty is agreeable by the university.

Knowledge-qualified, minimum warranties are otherwise provided by the university and this is generally accepted by the spin-out given the typically early stage of the technology. spin-out

It is recommended that the university warrants that it is duly incorporated, can enter into the licence, can perform the obligations within and owns the IP.

It is recommended that the university gives no other warranties, including no warranty that the licensed know-how has been, or will be, kept confidential, no warranty regarding the nature of the IP being licensed, for example whether it is or is not fit for purpose. Where relevant, it is recommended any additional warranties provided by the university are knowledge-qualified.

The university will often want assurance from the spin-out, (via a warranty or otherwise), that the spin-out has all the relevant IP from the university research group needed to deliver its business plan and exploit the licensed IP. The university wants to ensure the spin-out has all IP required to set it up for success. It also wants to discourage a situation where the spin-out takes licence to certain IP only (e.g. patent) and then accesses other IP outside of its granted rights (e.g. university data, protocols etc.). (This can be troublesome for later fundraising rounds when new investors undertake due diligence on the spin-out's IP).

This warranty will be relevant to the spin-out and founders at the spin-out's creation, though founders may drop out as the spin-out grows and matures.

Note: Although outside the scope of this table of recommendations, it is commonplace in the market for founders to cap their liability in relation to founder warranties in the investment agreement / shareholders agreement to one year of remuneration, or a slightly higher multiple of their remuneration.

3.3.11 Liabilities – as Related to Licence

Indemnities, warranties and liabilities are inter-related and should be considered with respect to each other.

A limit of liability is a must for the university, as a charitable, risk-averse organisation.

The Guide makes the following recommendations.

- A limit of liability for the university should be included in the licence. This is likely to be dictated by the university policy though the TTO may have limited ability to depart from it. Some universities prefer a fixed pound sterling amount, typically in the range (e.g. between £10k and £50k). Other universities cap their liability at the amount received by the university from the spin-out under the licence agreement (e.g. during a certain period of the term), subject to a fixed pound sterling minimum. Caps outside of this range may be considered on a case-by-case basis where strongly justified and a university may give consideration to their insurance cover in these situations. Where caps outside the recommended range are agreed, they should be time-bound. (Note: it may be countered that higher liability caps can encourage good practice and is in the interests of both parties to increase the liability cap. However, being risk-averse, universities will likely strongly oppose higher liability caps. It should also be noted later sub-licensees may request higher liability caps in which case the spin-out may subsequently assume some risk).
- Liability for indirect, consequential or special loss should generally be excluded.
- Deliberate breach by the university, express indemnities (if any are given by the university in favour of the spin-out), breach of CI, or matters which cannot be limited or excluded by law should be excluded from cap limit.
- Many university spin-out licence templates do not include a liability cap for the spin-out company. However, a spin-out will generally request a liability cap and this is a reasonable request. The same exclusions should apply as for the university's cap.

3.3.12 Ethical Licensing / Global Access

Ethical licensing is widely used by spin-outs, where the licence prohibits the spin-out from engaging with proscribed entities/bad actors (e.g. those associated with tobacco, child slavery, weapons of mass destruction etc.). This will likely be a university policy which may include a precise description of proscribed entities. For their own reputational protection, the spinout often readily agrees to an ethical licensing provision (see also Sub-Licensing).

Global access provisions are less widely accepted, though are on the rise. While parties agree global access is a 'nice to have' as part of the licence, in practice it may be financially and/or operationally challenging for the spinout to oblige with this provision.

For global access, the key focus is accessibility. Consideration should be given to the context of the technology and situation, (e.g. low-cost vaccine availability for low-to-middle-income countries) as well as potential resource availability (i.e. it is generally more meaningful to negotiate a global access provision with larger companies who are better placed to fulfil the obligation). While global access provisions may be a request of the university (potentially as a matter of policy), they may also be mandated by the funder with a requirement for relevant terms (e.g. step-in rights if not undertaken by spin-out) to be flowed through to the licence. In these instances, ability to comply with the obligations will in practice depend on raising substantial investment and one possible compromise is the global access obligation should be stipulated only to apply once the spin-out has raised substantial third-party investment exceeding a specified amount. However, this is another provision which the parties should be aware is likely to require extensive negotiation and be in no doubt that it will slow down the spin-out process. Parties aiming for a quick process would be well advised to keep things simple and avoid these more controversial provisions.

Glossary

4.0 Glossary

Assignment	A transaction in which property, rights, interests or benefits of a contract are transferred from one party (the 'assignor') to another party (the 'assignee') through sale or acquisition. An assignment may be incorporated in a standalone agreement or within a wider agreement where a contractual option can be exercised and other related items addressed.
Drag-Along/Tag- Along Rights	Drag-along rights are contractual provisions that allow a majority shareholder to force a minority shareholder to sell its shares under the terms negotiated by the majority shareholder in the event of a company sale (or equivalent event). Tag-along rights allow a minority shareholder to sell their shares in the event of a company sale (or equivalent) on the same terms and with the same buyer as the majority shareholder.
Employee Share Option Pool (ESOP)	An employee benefit where a company's employees can own shares in the company through a share option plan. Companies often use ESOPs to align employee interests with company interests, as working to create a successful company can mean a financial reward to the employee via increasing shareholding value.
Equity	The ownership in a company issued as shares with a monetary value.
Heads of Terms (HoT)	A non-binding document setting out key terms of a proposed commercial agreement or transaction between parties. Often referred to in the context of the licence agreement.
Patent Cost Reimbursement / Historical Patent Costs	Costs, fees and expenses incurred by the licensor for filing, prosecuting and maintaining the licensed patents and other relevant registered intellectual property rights up to the effective date of the licence agreement.
Improvements	Intellectual property that adds, varies, modifies or adapts any improvements to existing licensed intellectual property. Improvements may be non-severable, (cannot be put into practice without infringing existing patents), or severable (can be put into practice without infringing existing patents).
Intellectual Property (IP)	Creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. (Source: WIPO https://www.wipo. int/about-ip/en/)

Licence Agreement	A contract where one party (the 'licensor') provides another party (the 'licensee') permission and rights to use intellectual property which the licensee does not own for commercialisation purposes. The licensor may provide this right to the licensee to the exclusion of all other persons (exclusive licence) or with the inclusion of some other parties (non-exclusive licence).
Net Present Value (NPV)	A calculation of the current value of future payments from a company or investment over a period of time, using a risk adjusted discounted rate representative of a required rate of return.
Net Receipts	The aggregate of a licensed product's net sales and all net (sub-)licensing revenues received. (Note: net sales by a sub-licensee on which royalties are already due from the licensee to the licensor and milestones achieved by the sub-licensee in respect of which milestone payments are already due from the licensee to the licensor are excluded from net receipts amounts, when calculating net receipts royalties due to the licensor).
Net Sales	The balance due to a company from the invoiced sale of licensed products once deductions, such as costs, taxes, rebates etc. have been made. Exact deductions are often a point of negotiation.
Option	A contractual agreement between parties that reserves a right to enable a potential future transaction at a certain defined trigger point. The option, usually time- bound, gives the right to the potential transaction but not the obligation. Terms and conditions, including price and date, of the potential transaction may or may not be predetermined.
Pre-money Valuation	The valuation of the spin-out company prior to receiving external (e.g. VC) investment
Royalties	Legally binding fees due from a licensee to a licensor in exchange for the continued use of the licensor's intellectual property and other assets.
Royalty Stacking	Where a licensee is required to execute a royalty-bearing licence with a third party to avoid infringing the third party's patents in order to exploit the university-derived licenced IP, the licensee is allowed to reduce the royalty on net sales due to the university by a certain amount down toward a specified floor.

Spin-out	A new company formed primarily through the transfer of knowledge, technology, assets and/or people originating from the university, to further develop and exploit the technology. The university will ordinarily hold equity and/or is licensor of the relevant IP to the spin-out.
Start-up	A newly created business established by entrepreneurs who may or may not be from the university and may or may not be exploiting university-derived IP. The university will generally not have an equity share in a start-up, unless it is a spin-out.
Technology Readiness Level (TRL)	First developed by NASA to refer to the stage of development, technology readiness levels (TRLs) are measurement systems used to estimate the maturity level of a specific technology throughout its research, development and implementation pathway progression. The measurement system uses a scale of 1 to 9. In the life sciences sector for drug discovery activities, TRL 1 represents observation of basic scientific principles, TRL 5 represents investigational new drug stage (or equivalent) and TRL 9 is the most mature technology representing market launch and Phase IV studies. Also sometimes referred to as investment readiness level (IRL), the TRL rating gives an indication as to how much further development is required before the technology is a viable product.
Term Sheet	A non-binding document setting out key terms reached of a proposed commercial agreement or transaction between parties. Often referred to in the context of the spin-out company's formation.
Warranty	A contractual assurance provided by a party guaranteeing and confirming a specific situation exists. This assurance may be that the warranting party is legally able to enter into the contract, has control of the IP rights prior to executing the contract or some other situation. If the assurances are not true, the other party may be able to claim for damages against the warranting party for breach of warranty/breach of contract.

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TenU is an international collaboration formed to capture effective practices in research commercialisation, and share these with governments and higher education communities. Its members work together to increase the societal impact of research.



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Notes

