



# REVIEW OF THE LIFE SCIENCE AND HEALTH TECH INNOVATION AND COMMERCIALISATION SUPPORT LANDSCAPE

Executive Summary

Prepared by Fulcrum Direct Limited for Scottish Enterprise

## Executive Summary

### Introduction and Strategic Background

In November 2022, Scottish Enterprise commissioned Fulcrum Direct to undertake a review of the innovation and commercialisation support ecosystem for health innovation life science and health tech companies in Scotland. The Commission responds to certain recommendations in [\*The Campbell Report: a roadmap to investment for health innovation life sciences and health tech\*](#). Specifically, the work provides an evidence base to inform the implementation of Recommendation 14 of the Campbell Report:

“Conduct a review of the life sciences innovation and commercialisation environment in Scotland to explore opportunities for simplifying the process for companies to access domestic and international markets, including the regulatory landscape.”

In addition, by providing further analysis of the regulatory support environment it sought to inform Recommendation 12 of the Campbell Report:

“Test and develop an approach for providing support for Scottish SMEs to access advisors on standards and regulations.”

and Recommendation 13:

“Develop increased regulatory knowledge within the public sector to better develop policy and support industry.”

In addition to the implementation of The Campbell Report recommendations, the review aligns with, and can play a role in supporting delivery of, other key initiatives relevant to the health innovation life science/ health tech sector. These include a) two of Scottish Enterprise’s National Programmes - The Health for Wealth (HfW) National Programme and the Future Healthcare Manufacturing National Programme; b) SDI prioritised inward investment Healthtech opportunity area and c) activities of the Life Sciences Scotland Industry Leadership Group and its themed subgroups.

The remit of this Commission was to undertake a review of the support ecosystem and the organisations (generic and sector specific) currently providing innovation and commercialisation support to Scottish health innovation life sciences companies (including digital health companies), as well as the support for non-Scottish companies seeking to engage or set-up in Scotland. The focus is on human health covering support for companies seeking to access both health and social care markets and extending to support organisations operating at both Scottish and UK-wide level, where these organisations support firms based in Scotland.

Coverage included, but was not limited to, the following categories of enabler support:

- Private sector organisations including a range of commercial organisations and trade bodies.
- Public sector organisations including UKRI, Scottish Enterprise Agencies (SE, H&I and SOSE), NHS Scotland, organisations supporting innovation in the care sector, universities and innovation centres.

The research covered all stages of the company development continuum (pre seed/seed, spin out/start up, growth/expansion and mature) and all stages of product development (from initial idea through development and testing, support with standards and regulations up until regulatory approval, and subsequently to selling).

### **Methodology and Caveats**

The methodology utilised for this review commenced with a process of classifying ‘enabler’ support organisations likely to be required by companies, according to the type of service they provide. Thereafter secondary research was undertaken to populate this classification. The research identified 405 support enabler organisations. The dataset was further tagged by the enabler’s position in the company growth continuum; whether it operates locally, nationally or internationally plus website and company details, if available. The enabler classification and the support enabler organisations identified are listed in appendices to the main report.

There are important caveats related to the secondary research:

- The dataset of 405 support enabler organisations identified is a ‘snapshot’ of the ecosystem at the time of the research; it is not a definitive list of all enablers. It was agreed early in the project that full mapping of all available enabler organisations and their resources was neither practical nor achievable within the constraints of this Commission. As a result, mapping was undertaken to a level where it was deemed it would provide confidence that the subsequent analysis would be sufficiently robust to give a fair representation of the full enabler ecosystem. Fulcrum Direct believes that the level of mapping undertaken fulfils this “threshold of confidence” measure and, (when combined with the primary research and customer personas developed via this Commission) is representative of the overall support ecosystem available to Scottish companies.
- The objective of this Commission was not to update the resources contained within the [Scottish Health Research and Innovation Database \(SHRIE\)](#) database. Whilst SHRIE is a useful starting point, it is noted that there has been limited updating of the resources listed since its launch.
- For each enabler organisation, top level details are included in the Mapping Framework Database based on information provided on websites or through primary research interviews. It has not been possible to drill down into the specifics of each organisation or initiative given the volume of companies identified.

To support the findings from the secondary research and to provide a qualitative analysis of the ecosystem, 28 primary research interviews were undertaken (11 with support enablers, 17 with recipient companies). Topic guides were developed to provide structure and consistency to the interviews and these are included as appendices to the main report.

Finally, four customer personas were developed, deemed representative of health innovation life science/ health tech company needs at different stages of development (pre-seed/seed, spin out/start up, growth/expansion and mature) to simulate their customer journey within the current support landscape.

## Analysis

Analysis of the data in the dataset demonstrates that the support ecosystem provided by private and public sector organisations and by public sector organisations only is mainly split between pre-seed/seed stage of development and spin out/start-ups followed by support for companies at growth/expansion stage. This pattern is to be expected as companies require more support at early stages of development and less as they mature. Figures 1 and 2 show the percentage values for levels of support at all stages of development. Figure 1 includes private and public sector organisations; Figure 2 includes only public sector organisations.

*Figure 1 - Private and public sector support ecosystem for all stages of company development based on the number of organisations in the Mapping Framework Database (not definitive numbers)*

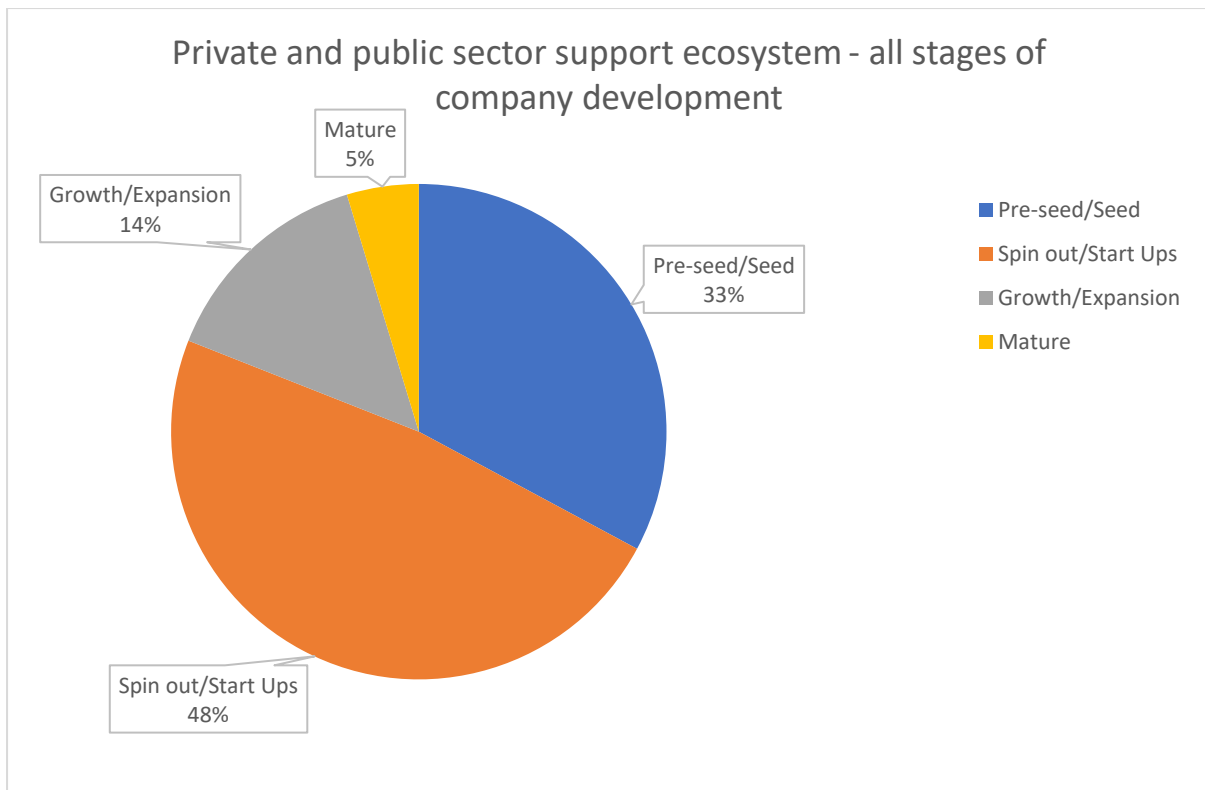
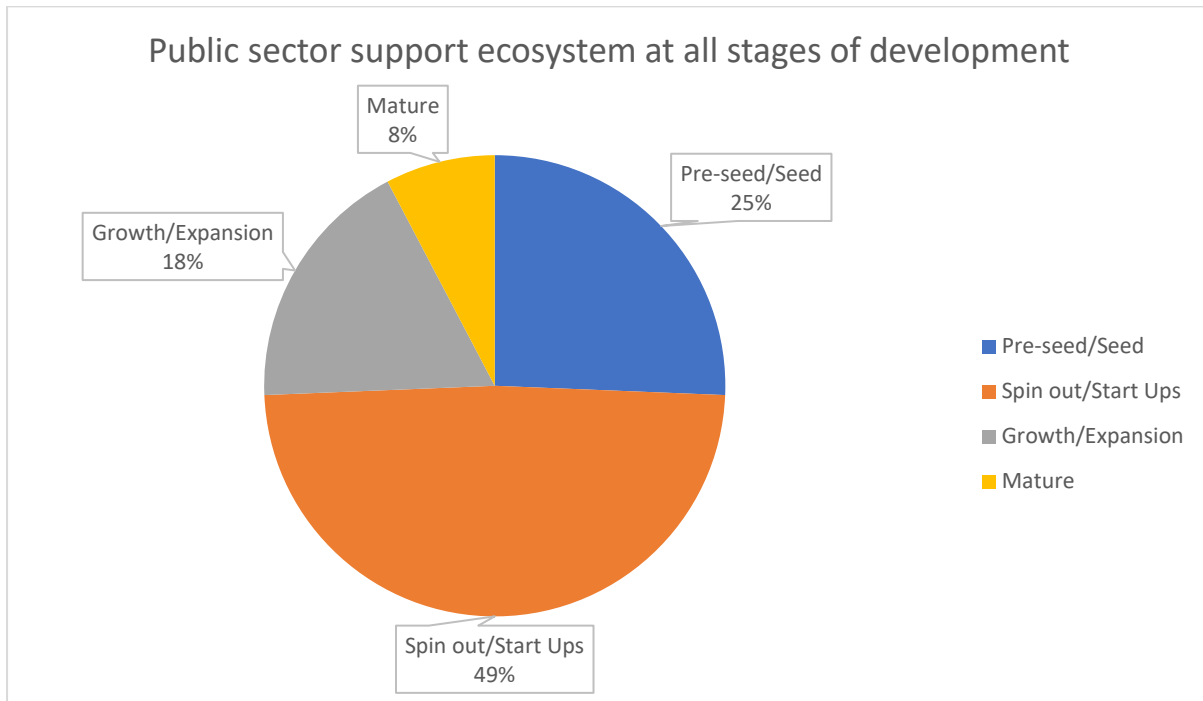


Figure 2 - Public sector support ecosystem for all stages of company development based on the number of organisations in the Mapping Framework Database (not definitive numbers)



There is however an important and underlying context to this research that should be noted - and that is the highly complex nature of the life sciences sector including healthcare innovation. The development journey of a health innovation life sciences/health tech company and the extremely wide variety of specific technical/clinical/device/disease variables in each company cannot be provided for in total in any support ecosystem. As a company moves along the continuum of its development, the 'cross over' between development stages is not clear cut particularly at the stage between pre-seed/seed and spin out. For example, technology development may stay in a university or have close connections to university research/specialist equipment capability even when a company is formed. Conversely a company may be formed, and new facilities used for technology development that is still essentially at the research stage. This complexity is likely to be one of the reasons that the support ecosystem may be perceived to need simplification. There is overlap in support provision between the different stages of the continuum which is an inherent part of this complex sector.

It should also be noted that recipient companies do not necessarily expect to find all support within Scotland and will comfortably seek support for their particular specialist technology from any geography where it is best provided. This is not perceived to be an 'issue' with the Scottish support ecosystem or a barrier to remaining in Scotland. It does not necessarily mean that companies do not perceive themselves to be 'Scottish' nor does it necessarily prevent them from basing themselves in Scotland and contributing to the Scottish economy. Many of the recipient companies taking part in the primary research confirmed that the support they receive may be from different areas of the UK and international support networks, without this causing them any challenges.

A further point endorsed by the primary research was that generic business support is relevant at a very early stage of company development as recipient companies don't have the balance of skills and come from a specific domain experience themselves. As these companies build their organisational structures their requirement for generic business support reduces and

their requirement for specialist support increases. Some interviewees said that all enablers need to understand the life sciences/health technology sector and that generic business support providers may not offer this specialism.

### **Customer Personas**

The personas developed covered the following stages of development:

**Stage 1 Pre-seed/Seed Persona** represents a customer in a typical organisation at this stage of development and may be described as an 'Academic Entrepreneur'. The support requirements for this stage are summarised as follows:

- Research expertise and access to specialist research groups
- Support organisations to help with setting up clinical studies to generate data
- Access to specialist equipment where required and/or lab space
- Grant funding (including bid writer support for applicants)
- Support for legal/regulatory requirements, including assessment of IP position and patents
- Market research and identification of 'beachhead market' and MVP
- There may be a requirement from grant funders to provide evidence of the commercial opportunity for the technology in development. Some/most of the support at this stage will be through the University and the tech transfer teams although specialists will also be engaged.

Figure 3 - Private and public sector support ecosystem for pre-seed/seed stage of company development based on the number of organisations in the Mapping Framework Database (not definitive numbers)

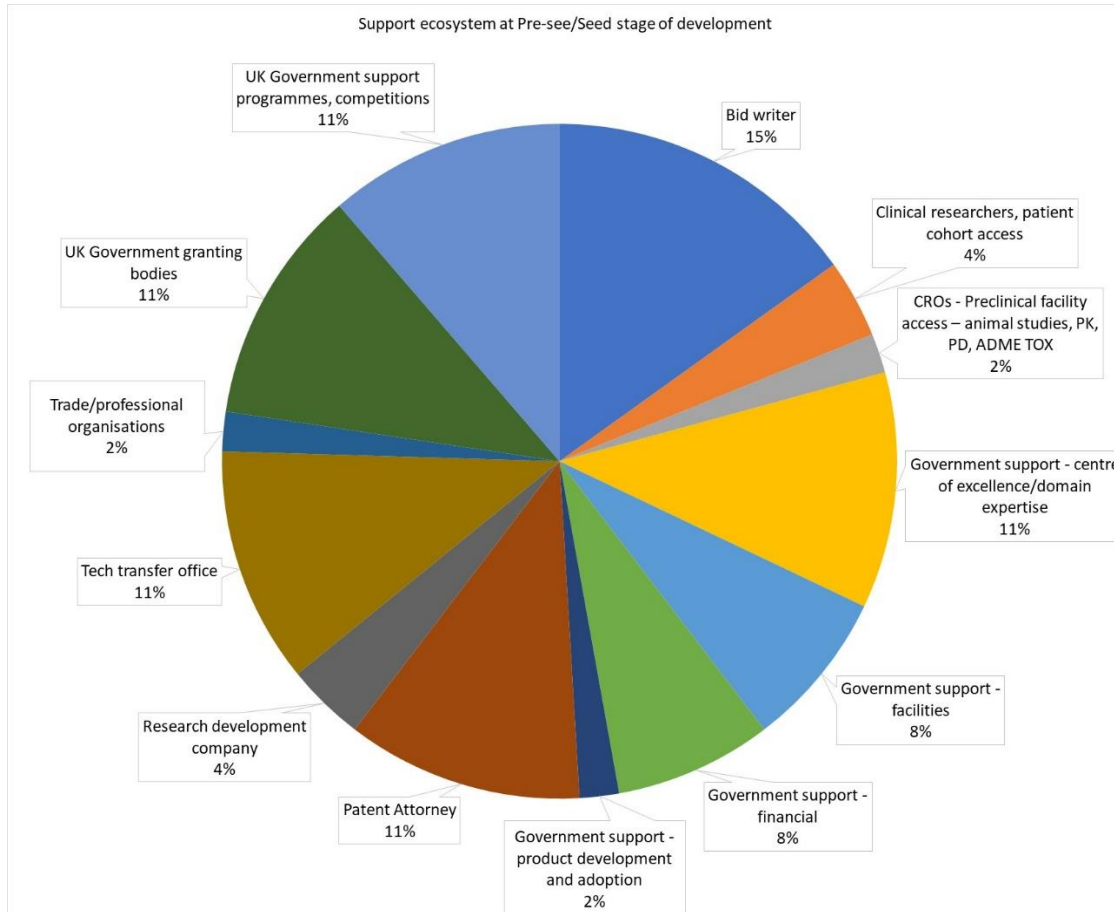


Figure 3 and the data behind it shows that, at this stage of a company’s development, there is a broadly even balance of support providers across each of the requisite functions from both private and public sector organisations, meeting the requirements outlined.

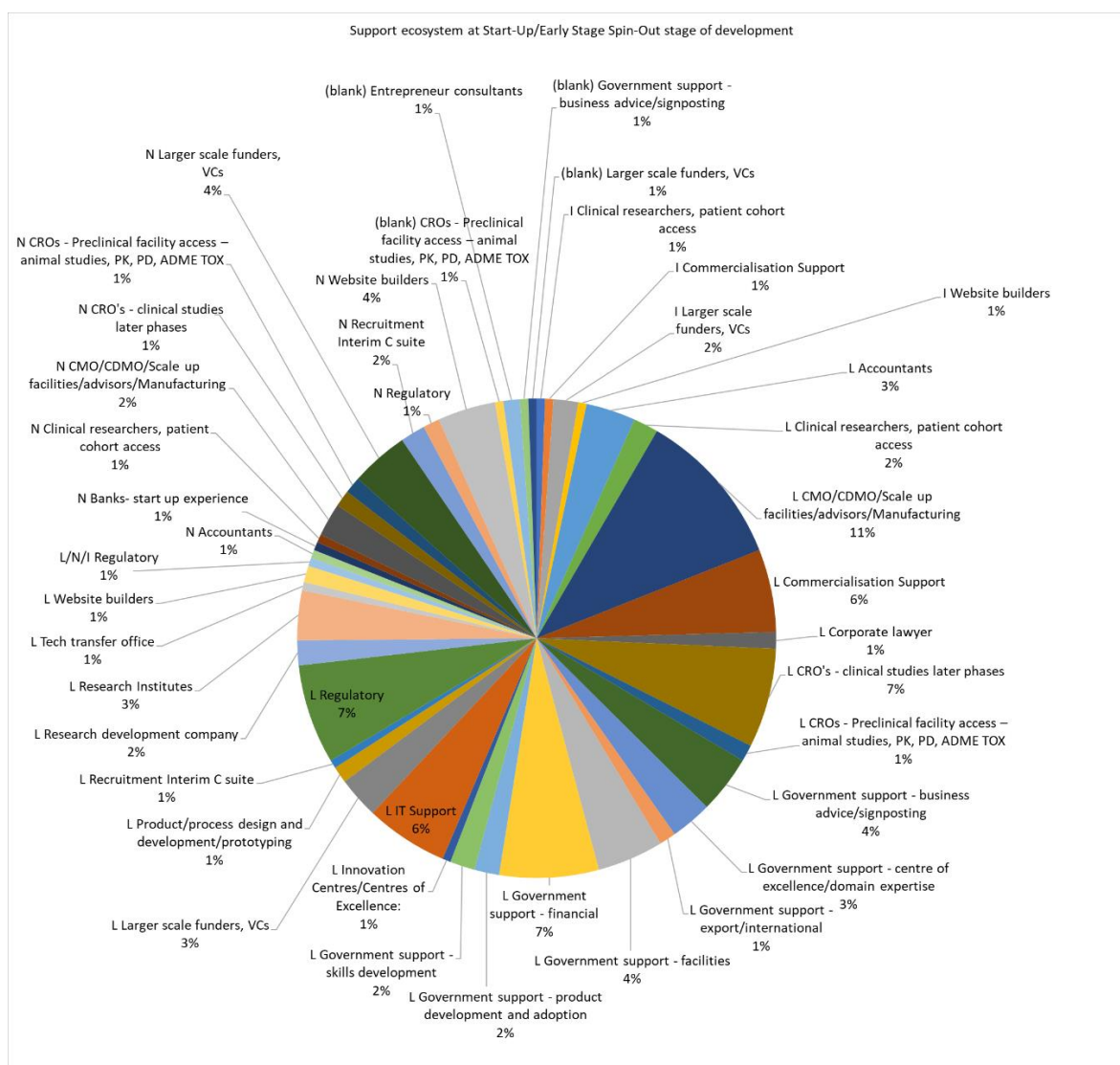
At this stage many companies are still linked to research groups and institutes in universities and services are provided by the university Tech Transfer teams and the specialist expertise and facilities within the universities. Access to financial support is key and there is a wide range of local, national and international grant funding sources available. These appear to complement each other well and support, in terms of knowing what funds are available, is well provided for through the High Growth Spin Out programme.

**Stage 2 Start-ups and Early-Stage Spin Outs Persona** represents a customer in a typical organisation at this stage of development described as a 'Start-Up Entrepreneur or Interim CEO'. Support requirements for Stage 2 are summarised as follows:

- Company is now incorporated, support required for commercial aspects as well as technology development including accountancy support and legal advice on the appropriate financial model.
- Further market research may be needed to focus on route to market and time to revenue generation.
- Interim CEO required to start shaping the organisation and most importantly to raise VC funding.
- Company looking for affordable premises which provide any specialist facilities needed. Accelerators and BioHubs are essential, and these may include business support functions as part of a package.
- Continued collaboration with university research groups and/or specialist research centres or centres of excellence.
- Further technical data to support regulatory submissions and to validate patent claims. If medical devices are being developed, regulatory advice will be required to ascertain class of device.
- Contract Research Organisations (CROs), Contract Development and Manufacturing Organisations (CDMOs) required together with clinical services for early stage 'healthies' studies and safety studies in disease cohorts.
- Recruitment of technical and development staff to carry out lab work and research volume.
- Funding at this stage could be seed funding and/or series A funding. Support will be needed to secure funding and help with pitching to VCs.



Figure 4 Private and public sector support ecosystem for start-up/early stage spin out stage of development based on the number of organisations in the Mapping Framework Database (not definitive numbers)



The support required at Stage 2 is more extensive and of a different nature to the pre-seed stage. There is a requirement for generic support to run a business as well as developing the technology. Further funding will be key. The mapping carried out for this report demonstrates that this support ecosystem is well provided for in Scotland with 179 organisations identified (and included on the Mapping Framework database) as providing support.

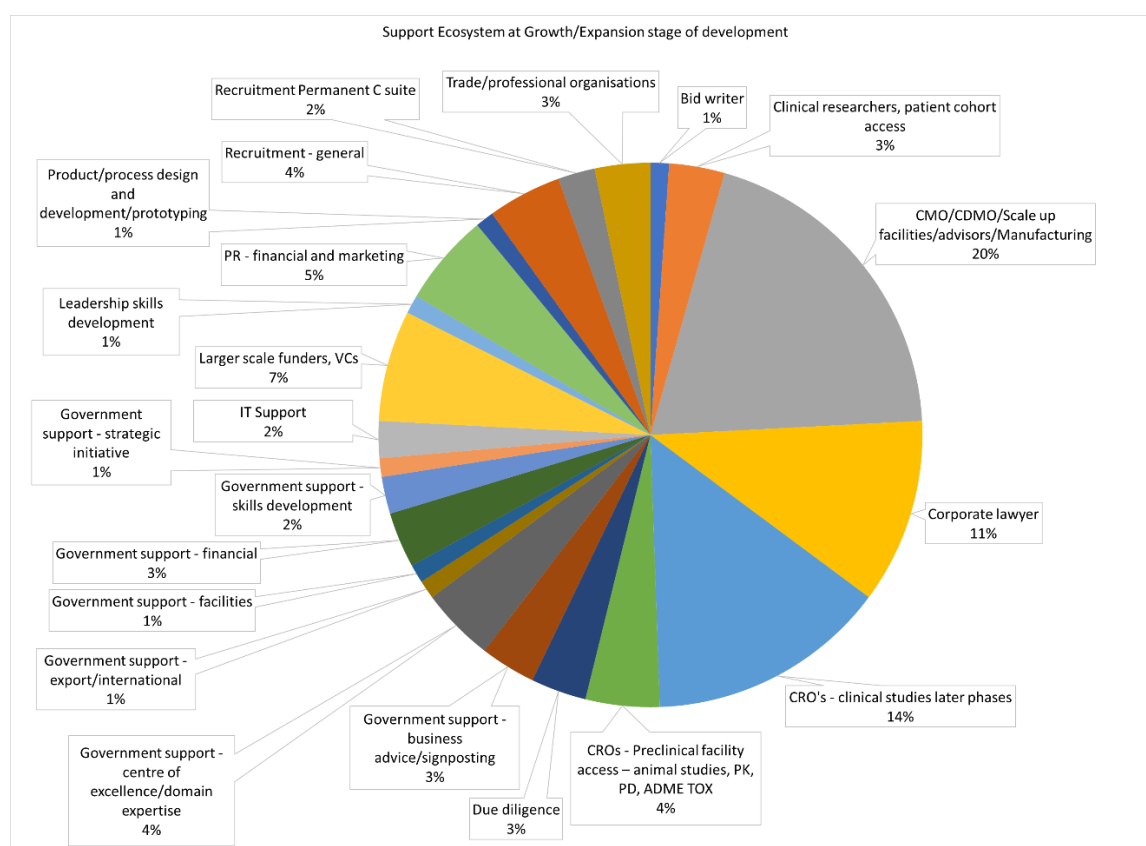
The 32 organisations included in the Mapping Framework database demonstrate a strong support network of organisations providing for the different commercial requirements including accountants, recruitment companies and lawyers as examples. VC funding is available at a local, national and international level and companies are accessing support outside Scotland as well as within Scotland. This is not perceived to be an issue. Requirements for further technology developments and clinical trials are provided for – again at local, national and international level – through CDMOs and CROs.

No noticeable gaps in the support ecosystem were identified possibly with the exception of banking organisations experienced in providing facilities for specialist requirements in life sciences. Hubs and accelerator facilities were mentioned in primary research interviews as a possible issue.

**Stage 3 Growth Company Persona:** The individual customer at this stage can be described as 'Development or Fast Growth CEO'. Support requirements at this stage cover:

- Larger Venture Capitalists or follow-on funding from a previous stage.
- Recruitment consultants and head-hunters will be required to recruit the Chief Executive (C) level team and establish the board and clinical advisory team.
- Business development support is required and a marketing team/outsourced marketing and PR support to release statements about technology developments and to meet investor statement requirements.
- NOMADS and brokers may be required at this stage for potential IPO.

Figure 5 - Private and public sector support ecosystem for growth/expansion stage of development based on the number of organisations in the Mapping Framework Database (not definitive numbers)

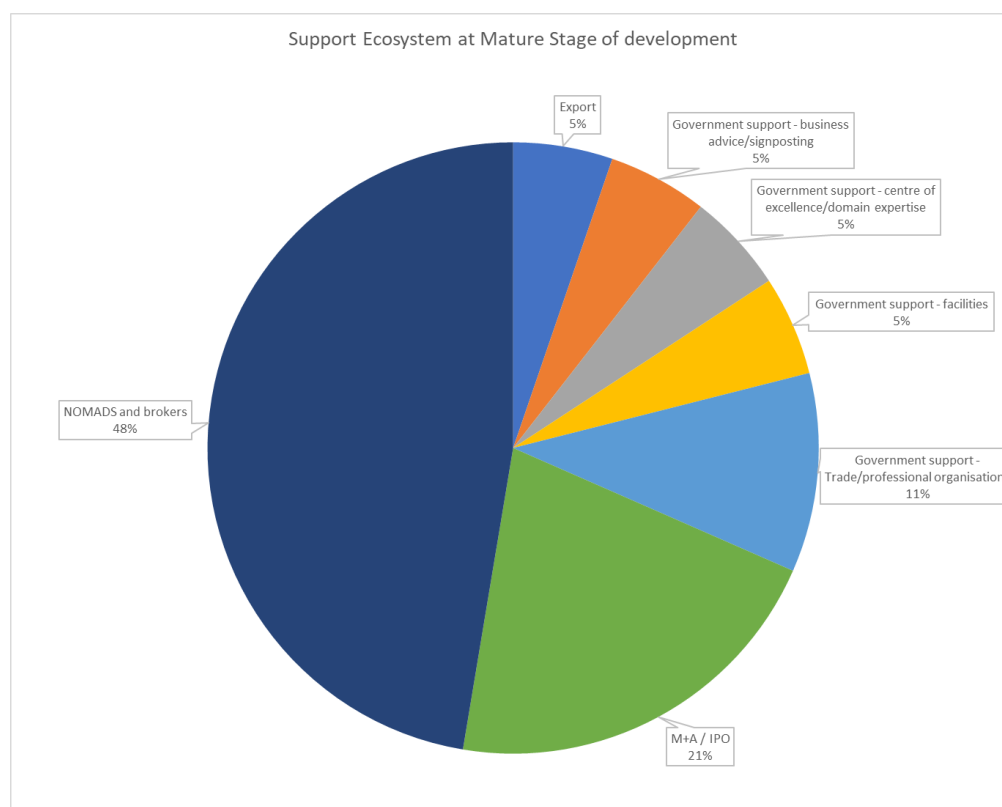


91 organisations were identified in the research as providing services at this stage and have been included on the Mapping Framework database. This indicates a strong support ecosystem for companies in the growth and expansion phase of development. One potential area needing attention is the provision of grow on space which was identified in primary research as an area of concern for some businesses.

**Stage 4 Mature Persona:** The individual customer at this stage can be described as a 'mature CEO'.

- The support requirements at this stage are quite different to previous stages. There is far less support required from the ecosystem but a buoyant ecosystem will be required to ensure a company at this stage remains in Scotland.
- It is important to retain established companies to, in turn, attract other companies to the region and to encourage the growth of indigenous companies at earlier stages of development.
- There will need to be a strategic imperative for the company to stay in Scotland - supply chain, availability of key skills, expensive manufacturing plant etc.

Figure 6 - private and public sector support ecosystem for mature stage of development based on the number of organisations in the Mapping Framework Database (not definitive numbers)



19 support organisations were identified in the research as providing services for companies at this stage of development reflecting that for mature companies it is less about how the ecosystem supports them, and more about their role as a vital part of the support network themselves. Mature companies form an important part of the life sciences healthcare innovation clusters throughout Scotland and will encourage other companies to relocate and indigenous companies to develop.

## **Regulatory Review**

Whilst the review of the regulatory support environment is an integral part of the overall Commission, there was a specific requirement to focus on regulatory support to inform Recommendations 12 and 13 of The Campbell Report.

The secondary research analysis undertaken of 36 organisations from both the public and the private sector. The private sector was based on the review of 13 enablers who are companies based in Scotland and described as regulatory consultants. Analysis of public sector organisations and trade bodies consisted of 23 organisations who had made some reference to regulatory support on their website. A list of the companies reviewed can be found in an appendix of the main report. The analysis concluded the following:

- The regulatory ecosystem is very complex and the requirements for each individual company are unique and often highly specialised.
- There may appear to be sufficient coverage in terms of regulatory expertise from a numerical perspective from these enablers, but deeper analysis of the services provided would suggest that specialised expertise sought by each company may not be available.
- Knowledge and understanding of the regulatory requirements within each company would appear to be incomplete and adequate planning and budgeting in a timely manner for this investment and resource challenge less well managed.
- The analysis and conclusions from this research align with the work carried out recently by ABHI that mirror the findings and recommendations of this project, namely: understanding complexity, developing a regulatory roadmap, publishing a directory of regulatory consultants and the provision of training and access to funding.

## **Conclusions**

This report has sought to provide the evidence base to inform the implementation of Recommendations 12,13, and 14 of The Campbell Report. Based on the secondary and primary research undertaken and the customer personas developed to test the research findings, Fulcrum Direct has derived the following conclusions, detailed under the following thematic areas;

1. Understand the complexity of the ecosystem
2. Define and document
3. Strengthen and invest in Knowledge
4. Harness and exploit
5. Fund
6. Communicate

### **1. Understand the complexity of the ecosystem**

The secondary research (mapping exercise) aspect of this Commission has endeavoured to define the ecosystem and the support organisations (enablers) required for life science/health tech companies. This goes some way to simplifying the categories of support enabler but not to fully define the specific or specialist support provided by each of them.

The secondary research has demonstrated that there is a wealth of support available to companies (405 resources identified via this research) noting that this is not a comprehensive mapping of the support landscape, but a snapshot researched for this Commission. In

comparison, the SHRIE database has circa 160 enabler companies documented. The relative volume of the enabler companies identified may account for any perception that the ecosystem is in need of simplification. The classification of these support companies will help in understanding which type of support is required when. The primary research highlighted the importance of relationships as a fundamental component of the support ecosystem – knowing who to talk to and who can sign-post to the most appropriate support at any given stage – is essential. The role of SE account management was highlighted in this regard, and it is recognised that other advisers across both the public and private sector are key in providing effective navigation through the ecosystem, although this also assumes that they are knowledgeable and experienced.

The Life Sciences/Health Technology sector is in many ways different from other commercial markets and requires expert knowledge to understand the ecosystem and to effectively signpost to the right support organisation to meet a company's highly specific requirements.

The breadth of technology that exists within academia in Scotland and from there, in the corresponding start-up companies is immense; considering pharmaceuticals alone, from small molecules through biologics, the variables in their mode of action and delivery form and mechanism as well as the plethora of diseases that may be targeted make this sector one of the most complicated in the world. Coupled with the fact that human health is at the core of these innovations, the regulatory burden in both safety and efficacy is significant.

The ecosystem is complicated, not regarding the broad level of service offered, but in its detail. The breadth of initial IP underpinning any company from unregulated software through medical devices and therapeutics, combined with clinical focus and disease state is a vast continuum that needs to be supported.

Further, the nature of the sector introduces complexity in its navigation, for example, an expert in medical devices will be unable to understand requirements for pharmaceutical development.

All of this technical complexity demands specific knowledge to understand companies' requirements and to effectively navigate and signpost through the ecosystem. As a consequence, the sector relies heavily on specialist support with experience relevant to the company's innovation and target sector. The support requirement starts early and so intervention with accurate signposting and expertise also needs to be timely.

Support requirements for companies is a combination of generic and specialist – it moves from generic to highly specific as a company moves along the development continuum and the balance changes as a company matures. At the early stages, there may be some duplication in support provision where similar functions are provided by a range of suppliers including both public and private sector organisations. The risk of duplication is more likely to occur where more generic business support services are provided rather than specialist ones for example Business Gateway, individual commercial consultants and the incubator support from, for example, Edinburgh BioQuarter and ONE Life Sciences.

The support sought must be relevant to the stage of the company's development and its specific technical requirement. The company may source this expertise in Scotland, or it may need to go national or even international to find the right skills. This may only be perceived as a problem if the company does not have budget to fund this recruitment.

The research carried out in this study goes some way to describe the ecosystem and its unique requirements and to define what resources are needed to ensure a successful and thriving sector.

## **2. Define and document**

Given the complexity, there is a requirement to fully define and document all enabler support organisations (and their specific offerings) such that recipient companies are fully informed of where their required support may be obtained. An accurate, up to date and curated online resource is an essential requirement as a basic tool to support the ecosystem.

This provides economic benefit to the companies that seek the support and gives opportunity to suppliers of services within Scotland to further support the ecosystem.

## **3. Strengthen and invest in Knowledge**

Both the secondary and primary research supported the essential requirement for specific skills and expertise to support the sector. Because of the specialist nature of the sector and the unique requirements of each company, the skills required change as companies develop along the continuum with the need for specialist support outweighing that for generic support as the company grows. At the outset companies tend to require commercial skills as technical skills are often with the founders, particularly if they are academic. Bias towards more particular and unique specialist skills, including regulatory knowledge will develop as each company travels along the continuum.

The account management system provided by Scottish Enterprise works extremely well as the experienced account managers are able to signpost companies to appropriate funding as well as having knowledge and expertise of the ecosystem. Primary research particularly highlighted the need for it to continue and potentially expand.

## **4. Harness and exploit**

There are great strengths within the sector and in particular the academic engine that generates ideas and seeds companies is very strong. Some relationships already exist between the members of the ecosystem but these need to be tapped into and further exploited. The following provides some examples.

- Networks of interim CEOs already exist that are managed by the technology transfer departments of the universities with life science and healthcare IP portfolios. These can be more actively engaged to support the commercialisation of this IP.
- There is unmined nascent IP within the universities that can be further exploited.
- NHS market access for product development and evaluation potential is unexploited as well as procurement pathway being difficult to navigate.
- More facilities are required with specific infrastructure for early stage and grow on companies. The ones that exist are full.
- International relationships have already been established with the Scottish diaspora with the likes of GlobalScot but these should be further exploited.
- There are several globally recognised very mature companies based in Scotland, their retention should be ensured perhaps with a more formal anchor company concept.

## **5. Fund**

Identified by the secondary research and further endorsed by the primary research interviews, the initial funding of start-up companies and their funding continuity is critical. There are gaps in the continuum, one at the earliest stage, where non-dilutive funding is ideal and another at

the fast growth stage Series B onwards where companies are looking for larger funds between £2M and £10M. The High Growth Spinout Programme (HGSP) works well as a buffer for the early stage gap and is critical to company success, however a limit to the number of companies that win entry to this programme and those that don't struggle to bridge this gap. Companies at Series B stage almost always source this funding out Scotland and this may result in companies relocating elsewhere.

## 6. Communicate

There is a fundamental requirement to communicate all of the findings of this report to understand the ecosystem itself and the already existing support systems that constitute it. Further to this, all of the conclusions of the research documented above will have a requirement to communicate information to the ecosystem through a co-ordinated programme. The primary research interviews all referred to communication associated with different aspects of the ecosystem and its support. These have been documented in the above conclusions and, without an effective communication platform, these issues will continue.

### Recommendations

Linking to the above thematic conclusions, Fulcrum Direct would suggest the following recommendations are considered as a way of simplifying navigation of the complex support ecosystem for health innovation life sciences/health tech companies in Scotland.

<b>Recommendation 1: Understand the Complexity of the Ecosystem</b>
R1: Complete the mapping of organisations currently providing innovation and commercialisation support to Scottish health innovation life sciences companies (including digital health companies)
<b>Recommendation 2. Define and document the ecosystem</b>
R2a: Following on from R1, build a definitive database, merging all available sources of support to provide a complete map of the support ecosystem for Scottish companies and ensure it is refreshed, updated, curated and crucially, promoted widely
R2b: Build a library of support 'How to' Guides to develop the support ecosystem. These may include a regulatory document, funding guide and a list of interim CEOs
<b>Recommendation 3 - Strengthen &amp; Invest in Knowledge</b>
R3a: Strengthen and Invest in knowledge of the support ecosystem by ensuring there is sufficient understanding and expertise of it within advisory teams at all levels
R3b: Consider offering supplementary training to company founders to bridge the gap between founders alone and their first commercial recruits. These training facilities already exist within incubators and through training providers too with a concern regarding possible duplication. Co-ordination of this provision may de-risk companies at the pre-investment phase. Consider offering small training grants to company founders to supplement their business skills and engage external consultants
R3c: Linked to R3a, consider the development of the account managed service and the opportunity to further build specific expertise. Consider how services can be widened to companies who are unsuccessful in selection for the High Growth Spin Out Programme (HGSP)

**Recommendation 4: Harness and Exploit – network, connect, collaborative relationships**

R4a: Formalise and document the interim Chief Executive Officer (CEO) network in Scotland . This can be extended to include other board positions in start-up companies as well as Non Executive Directors (NEDs).

R4b: Continue alignment with University tech transfer leads and consider allocating resources to ‘mine’ the pipeline and ensure investable opportunities are not lost

R4c: Continue to actively engage with NHS Scotland to create opportunities for technologies developed in Scotland to have increased opportunity for implementation within the NHS and to leverage international opportunities

R4d: Provide visibility of the development of incubators associated with universities and geographically to ensure balanced coverage

R4e: Encourage companies to look internationally for their opportunities at the earliest stage. Continue to utilise the GlobalScot network and other diaspora networks internationally to target senior executives with an existing interest in Scotland

R4f: Support the interaction between mature anchor companies in Scotland and their local universities to offer transition training from the university lab to the commercial lab

**Recommendation 5: Fund**

R5a: Create an investment “template document” for spin out companies to understand the funding landscape (as part of R2)

R5b: Continue investment support programmes including the High Growth Spin Out Programme and other investment and innovation support programmes. Consider ring-fencing a Health Life Sciences/Health Tech sector funding pot

R5c: Funders to develop a clear strategy regarding following investment in subsequent rounds of investment to avoid dilution and further to develop a clear exit strategy that would ensure that successful investments will re-cycle funds to reinvest. Consider ways to reduce the administrative burden of applying for funds (as part of R5a)

R5d: For larger scale investments and to bridge the second Series A to Series B funding gap, consider running investment road shows; organising investment events or supporting trade missions to investment fairs

**Recommendation 6: Communicate, Raise Awareness, Increase Visibility & Transparency**

R6: Create a communications strategy and action plan to support the implementation of the recommendations in this report and in order raise awareness and increase visibility /transparency of the support available amongst all ecosystem players

**Recommendation 7 - Regulatory focus - A unique challenge**

R7a: as part of R1 create a sub section of the database documenting the regulatory support network available to Scottish companies, covering both Scottish-based resources as well as those that exist outside Scotland



R7b: As part of R2, develop a high-level guide describing to early-stage companies what a regulatory journey for a life science company would entail

R7c: Linking to R2, R6 and R7b, ensure at the earliest stage of a company's establishment they are aware of the legal responsibility to conform to all regulatory requirements as appropriate to their device or drug

R7d: Consider the allocation of resources within advisory teams to act as "champions" in navigating and signposting companies to the relevant support and how to access this