

Re-shaping UK Life Science Commercialisation

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The Challenge

The Research & Development Society has been running an intensive programme over the last 6 months, to understand the most significant challenges and potential solutions within the UK's Life Science ecosystems. This initiative has integrated the RDS' extensive expertise in R&D strategy and innovation management, new data collected from RDS surveys, and data provided by its partner organisations, augmented by close consultation with key stakeholders in life science ecosystems across the country.

The timing of this report is critical because the UK government has made Life Sciences a key component of its industrial strategy, assigning it significance as one of the Industrial Strategy growth-driving sectors (IS-8)¹. This focus rightly recognises that the UK is well positioned to be competitive in this sector. The Government has also recognised that despite the nation's success in innovation; it struggles with commercialisation and adoption: However, there are still problems with how the UK government is tackling the commercialisation challenge in the Life Science sector. A failure to accurately identify the gaps in the commercialisation models of UK companies is leading to misdirected support that fails to tackle the complexities of the challenge.

Our research confirms that the period spent focusing on the development, implementation and iteration of a viable business model (referred to as Chasm II² going forward), is where most companies face the greatest risk of failure. While government has placed more focus on technology adoption and exports, they continue to hold a narrow perspective that fails to tackle the wide range of factors which will drive growth.

Principal Conclusions

Our research confirmed the broad picture embodied in the Triple Chasm Model (discussed in detail in the Annex below):

- The growth trajectory of UK life science companies shows the same diffusion-driven growth curve for all geographies and market spaces, with discontinuities at Chasms I, II and III.
- The UK has a very strong science base in life sciences with the majority of reporting companies clustered around Chasm I.
- The UK shows a significant decline in the number of companies and products around Chasm II and beyond.

¹ https://www.gov.uk/government/publications/industrial-strategy/industrial-strategy-sector-definitions-list

² https://www.triplechasm.com/what-is-new/136/tackling-the-growth-challenge-we-need-to-focus-on-chasm-ii-



Differences between the companies along the commercialisation journey can be explained by the nature of the products and services they are focused on. In particular, the five categories of products and services in the data set, defined by function **rather than form**, confirm the key challenges in commercialisation faced by companies:

- Many companies are working on developing new biomarkers, but those working on developing platforms and tools appear to be more successful than those still focusing on fundamental research, although the reported data suggests serious funding challenges.
- 'Conventional' diagnostic companies seem to be doing best, as their approach is based on well-established routes to market.
- 'Prognostic' companies appear to face big challenges, based on understanding how 'preventative' health care will be delivered. This is a real problem due to customer perceptions, which are also affecting investor sentiment.
- Therapeutic companies have well-established pathways to market but the key problem here is long timescales driven by clinical adoption pathways as well as the high risk of failure in the clinical trials process.
- Services companies seem to be relatively successful at crossing Chasm II. The
 data shows that service-based business models are largely funded by customer
 revenues compared to other types. Unfortunately, however, these businesses
 also have the lowest growth potential because they can't scale customer
 numbers easily.

This data confirms why there is a gap between a strong science base and relatively few growth companies in the UK life science eco-system. The data also confirms that tacking this challenge requires a multi-polar approach not a bi-polar approach based on just looking at science and technology innovation and funding.

UK Life Science ventures are failing to take a holistic approach to their own commercialisation, often continuing to place significant focus on technology development at the expense of other more critical factors. Companies at the later stages of commercialisation, trying to cross Chasm II, were asked to assess themselves across each of the twelve vectors defined in the Triple Chasm Model. Across nearly every vector, these companies fell short of the benchmark values determined from a diverse set of successful companies. Factors relating to distribution, marketing, product/service synthesis and business model development are all factors of particular concern. Recently announced government support is moving beyond just technology development and investment but there are still gaps in the types of support given.



Our Recommendations to Tackle this Challenge

The conclusions of our research lead to a broad set of recommendations, covering a broad area. but we can group them into three key areas:

- There needs to be a clearer focus on how resources are allocated at the national level. The new industrial strategy has made numerous new funding announcements but there are stills gaps that must be addressed
- As more powers are transferred to local authorities, it is an opportune moment to focus on developing new and existing regional ecosystems. Nurturing these clusters will require an integrated approach including mapping commercial entities and designing new forms of intervention
- Intervention agencies can better target their support with an improved understanding of the trends affecting different product types within the life science sector.

Re-shaping Resource Allocation at a National Level

With new investment and attention directed towards emerging markets and the NHS it is particularly important that it we allocate our resources to provide the maximum impact. Recent announcements have shown the government is taking this issue seriously but there are areas where more should still be done. The treasury has indicated the importance of generating crowding-in funding to support its strategy but has not yet provided a clear explanation of how this can be done in practice. Leveraging data to mitigate risk profiles and embracing new business models would be a starting point in tackling the challenge.

As one of the largest national healthcare bodies in the world, the NHS could be a pioneer for the deployment of new healthcare products and services. However, new technology integration continues to be hampered by difficult clinical adoption pathways. Here the Life Sciences Sector Plan³ seems to be moving in the right direction with a full embrace of implementing the O'Shaughnessy reforms⁴ and strengthening links between Integrated Care Boards and industry.

Finally, more urgency should be shown in the reform of regulation within the life sciences and across key pervasive technologies. The creation of the new Regulatory Innovation Office shows promise, but we are still waiting for major announcements on the implementation of life science regulatory reform. Technology-enabled SMEs in this

https://assets.publishing.service.gov.uk/media/688c90a8e8ba9507fc1b090c/Life_Sciences_Sector_Plan.pdf

⁴ https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review-final-report



space are regularly faced with the challenge of high-costs to achieve compliance⁵ with national and international regulations leading to many ventures failing to find a stable footing. With the prominence of AI in the government's plans, it is also surprising that clarity on UK AI regulation is still hard to find. Many new life sciences SMEs are already making heavy use of these new technologies but fear future changes that could make their business models obsolete. Maintaining this ambiguity will lead new and existing ventures to hesitate before fully deploying AI when it might be appropriate. Of course, aligning and competing with other markets should be a priority throughout this process as we push to maintain technological sovereignty through incentivising companies to commercialise within the UK.

Ecosystem Development at a Regional Level

With the current devolution agenda and ongoing emergence of new combined mayoral authorities, there will need to be greater attention paid to how growth policies are developed at a local, as well as national, level. Each of these ecosystems will find themselves with their own challenges and opportunities but there are common approaches that could have significant impact.

The first concern of importance to new, and many existing, regional authorities will be a granular mapping of the current state of their respective ecosystems. Mayoral combined authorities will, of course, need to account for every market sector but more sector focused bodies like the Academic Health Science Networks can prioritise a narrower slice. Deploying appropriate metrics will deeply impact the value of the data collected. Most importantly, a well-chosen maturity mapping model that includes ventures from early-stage prototype development all the way up to full scale deployment, based on Commercialisation Readiness Levels (CRL), will allow mature and emergent sectors to be clearly distinguished and provide a better understanding of the support required at different stages. Further nuanced insights can expand on these insights through the use of an integrated profiling framework and a carefully chosen product type taxonomy.

The understanding gleaned from this exercise should reveal numerous insights but from our research it seems safe to assume that the same Chasm II challenge will be observed. Local organisations with a focus on commercialising technologies must therefore shift their focus from innovation to adoption, leveraging public and private resources to support mid stage enterprises. Technology Readiness Levels (TRL) are commonly used by UK innovation agencies to evaluate maturity, but the measurement scale stops short of the point when the development of a viable business model becomes critical. Technology Transfer Offices in particular could play a key role in leading this shift by ensuring university spinouts to consider later stage challenges from the start of their development.

⁵ https://www.rdsoc.org/blog/protection-or-protection-racketeering-medical-device-regulators-are?categoryId=459823



Finally, new forms of interventions need to be designed and implemented. These need to benefit from input by all the key stakeholders including investors alongside public & private customers. They should focus on the Chasm II challenge, prioritising companies at CRL 5+ that are no longer prioritising technology development but require a more holistic approach to support commercialisation. Trends identified from multi-vector profiling will allow the areas that require the most support to be managed and help support new innovative business models in emergent markets by providing evidence to mitigate risk profiles. Efforts to deploy these types of intervention have already begun, for example by Health Innovation East⁶.

Developing New Forms of Support at Intervention Agency and Company Level

Intervention agencies need to think more broadly about how they support companies they are working with and review three key areas. First, the provision of physical resources such as offices, labs and infrastructure, including data processing facilities. The delivery of active intervention guidance: existing support based on accelerators are useful but the real challenge these companies face lies at Chasm II; Intervention agencies need to consider the provision of interventions like the Reactor previously piloted by the Triple Chasm Company. Finally, they need to address access to deep expertise organised by vector rather than just generalised support provided by networks consisting of successful entrepreneurs and senior management previously employed in larger successful companies. These challenges are mirrored by the companies themselves, who operate within the support environment provided by the intervention agencies-but the data from our research suggests that more work needs to be done to educate the leadership teams of these companies, and to provide them with more structured intervention support covering all 12 meso-economic vectors.

Ventures in the life science sector will need to design their strategies depending on their unique positioning and product/service synthesis. Using our research into the trends affecting different product types we can identify some of the challenges that need to be addressed. Comprising the largest share of our dataset, therapeutics continue to suffer from long time scales to achieving adoption and while prominent at earlier maturities, show the largest drop-off as CRL increases. Additional investment to these companies is often only seriously considered with sufficient clinical efficacy data to minimise portfolio and investment risk so, streamlining trials and providing greater financial support at the later stages may prove beneficial. Platforms & tools, on the other hand, show a relatively even distribution by maturity but still experience funding challenges especially because many investors still want to focus on the deployment of targeted diagnostics and therapies rather than more generic capability. Diagnostic focused companies benefit from well-established routes to market and as a result do not appear to be dramatically impacted by the new emergent market structures in the life sciences. Prognostics, while less represented in our dataset, also appear to be struggling to reach

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⁶ https://healthinnovationeast.co.uk/innovators-scale-up/



high maturities. This may be due to the emergent market structures around 'preventative' health care. Limited customer perceptions may be impacting investor sentiment and advocating to improve user receptiveness to the new business models may help. Finally service focused companies, by contrast, are the most effective at maturing. They are largely funded by customer revenues rather than investment but unfortunately show the lowest growth potential due to the difficulties in scaling.

Future Work on Monitoring Commercialisation

Our investigation into the Life Science ecosystems across the country has drawn upon lessons learned in previous programmes and will continue to inform our work going forward. We have improved our data collection strategy through collaboration with local partner organisations in the main regional clusters across the UK: Cambridge, London, Oxford and Stevenage in the Golden Triangle; Greater Manchester, Liverpool and Birmingham in the North-West Cluster; and Bristol and Bath in the South-West Cluster. This clearly needs to be extended to include North-East England, Scotland and Wales.

Our future programmes will draw on these lessons and seek to expand and refine our data collection further. We will incorporate feedback on the design of our survey questions to increase the ease of completing them and optimise the quality of data collected. With the combined data we have collected ourselves and that were provided by our partners, we now have a viable base dataset that we can build upon to test our conclusions and incorporate new considerations.

We aim to collect more rigorous longitudinal data that can provide a picture of how the UK life sciences ecosystem is changing over time. We will reach out to universities and technology transfer offices to gain better access to earlier stage ventures with the intention of widening our dataset.



Annex

Our data collection and analysis was guided by a meso-economic approach, using the only robust model available, based on the Triple Chasm Model, a framework for understanding and analysing the commercialisation of new products and services as they mature. The model was born out of an intention to develop an integrated multipolar system for tracking and evaluating new technology enabled firms through their commercialisation journey, avoiding the pitfalls of placing excessive focus on just one or two particular factors.

The model consists of three key components. Defining the three discontinuities in the diffusion-driven growth of any science and technology enabled product are the "chasms". Tracking over 3000 companies and associated products, across different geographies and market sectors, allowed their customer numbers to be plotted against time. Normalising this data by the expected maximum number of customers and time to reach full maturity revealed consistent trends and three notable drops in the rate of customer growth. These stationary points correspond to spikes in venture failure rates and were defined as the three chasms. Chasm I indicates the challenges in creating a successful prototype that is ready to begin testing or demonstration with protocustomers. Chasm II is defined as the period during which a venture develops and tests its business model with the intention of producing a commercially viable product. Finally, Chasm III refers to the process of developing a strategy to scale-up the business model to full commercial deployment. The spikes in failure rate are notable at each chasm but importantly are far more prominent around Chasm II than Chasm I or III.

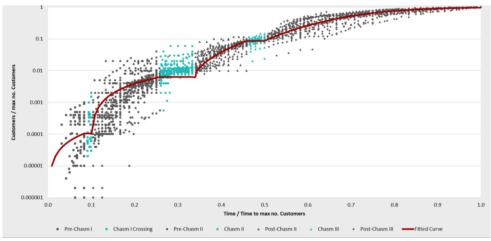


Fig 1. Cumulative Customer Growth - 'stitched' into single normalised growth curve

Tracking products & services as they commercialise requires a more nuanced structure than just the three Chasms. For this the framework deploys its second key component, the use of Commercialisation Readiness Levels (CRL) to track maturity. Technology Readiness Levels (TRL) have commonly been used by innovation agencies to evaluate the maturity of products in their portfolios, but this approach ends at the point when the proto-product has been successfully tested. This is particularly important as it means TRL does not cover Chasms II or III, resulting in non-technology related factors being ignored and limiting the ability to track maturity at later stages in the innovation process.



CRLs on the other hand, extend all the way to full maturity, covering all three Chasms and focus on commercial as well as technological maturity, which is critical when we consider the impact of innovation on economic growth. This approach also allows data to be aggregated to provide a broader understanding of portfolios, clusters and even national trends.

CRL*	Commercialisation Readiness Level Definition											
0	You are doing research on fundamental science and technology building blocks that could have a future application.											
1	You have started the process of thinking about how your science and technology could lead to a future product or service.											
2	You have identified a specific opportunity space where you could create a new product or service.											
3	You have created a product or service concept for the identified opportunity space.											
	CHASM I											
4	$You have successfully tested your completed prototype or demonstrator with {\it proto-customers} \ .$											
5	You turned the prototype into a functioning product or service which reflects the feedback from <i>protocustomers</i> and it is generating initial revenues with <i>charter customers</i> .											
6	You have a product or service ready for deployment with <i>charter customers</i> with clarity on functionality, packaging, and pricing, and you are exploring different <i>business models</i> and <i>channels to market</i> .											
	CHASM II											
7	You have demonstrated acceptance of your product or service with <i>charter customers</i> and you have developed a <i>sustainable business model</i> with ideas for potential <i>channels to market</i> .											
8	You have figured out how you are going to move from <i>charter customers</i> to <i>mainstream customers</i> , and you have defined your <i>channels to market</i> to support your <i>sustainable business model</i> .											
9	You are ready for full scale deployment with <i>mainstream customers</i> with the functionality, packaging, pricing, <i>business model</i> and <i>channels to market</i> pinned down.											
	CHASM III											
10	You are in full scale deployment with mainstream customers based on a sustainable business model and clear distribution strategy.											
*	Commercialisation Readiness Level (CRL) adapted from NASA Technology Readiness Level (TRL) approach											

Fig 2. Commercialisation Readiness Level Definitions

Finally, the Triple Chasm Model's set of meso-economic vectors allow for multi-polar analysis accounting for all of the relevant growth factors. These twelve vectors are organised as internal, external and composite vectors. Internal vectors are mostly influenced by the company's workforce themselves. External vectors, however, are heavily influenced by market forces and macro level drivers. Handling them, therefore, is a matter of accounting for and responding to external forces. Composite vectors operate at the intersection between the two, focusing on how to position a product/service within a market and define its overall business model. The relevance of each vector changes with maturity, allowing for powerful comparative analysis. The Triple Chasm Company have assessed benchmark scores for each CRL based on over 300 successful ventures. This allows companies to evaluate themselves at their current maturity and identify gaps between their current execution and the performance they need to achieve to reach the next CRL. At the individual product level this inevitably leads to bias due to the subjective nature all the vectors but can still prove instructive to the subject. Given sufficient sample size, however, larger trends begin to emerge and provide more reliable insight.



External Vectors	Composite Vectors	Internal Vectors						
E1. Market Spaces Qualitative articulation based on players & relations: Spaces vs Segments vs Industries Market space-centric value chains		I1. Technology Development & Continge Deployment Quantitative approach based on Relevan & Execution Scores						
E2. Proposition Framing, Competition & Regulation Qualitative Mapping Proposition, Competitors, Regulation, Partners & Suppliers versus market space centric value chain	C1. Strategic Positioning Qualitative Approach based on Strategic Mapping Tool	IP Management Quantitative approach based on Relevanc Execution Scores						
	Quantitative approach based on Relevance & Execution Scores	13. Product & Service Synthesis <i>Quantitative</i> approach based on Relevance & Execution Scores						
E3. Customer Definition Qualitative Focus on Market Typology and Customer Behaviours	C2. Business Model Qualitative Approach based on defining assessmedel architecture	14. Manufacturing & Deployment Quantitative approach based on Relevance & Execution Scores						
Quantitative Estimates of customer numbers, customer-user ratios	and components Quantitative approach based on building detailed spreadsheet model covering revenues, costs, funding and	15. Human Capital Quantitative approach based on Relevand & Execution Scores						
E4. Distribution Marketing & Sales Qualitative focus on channel selection Quantitative assessment of key go-to- market criteria and relative impact of the m7Ps	cash flow	I6. Financial Capital Qualitative Approach to Options Quantitative approach to valuation and amounts raised						

Fig 3. The 12 Meso-economic vectors

These tools were incorporated into the "Life Sciences Ecosystem Mapper Survey" which was shared with RDS distribution partners and the companies themselves throughout the UK. This survey was split into 5 sections. Section 1 requested basic information from the submitter (name, role, etc) and basic information of the venture they were involved in such as the number of full-time equivalent employees and its geographic distribution. Section 2 focused solely on their product, assessing the size of their portfolio and the type and CRL of their primary product. We also obtained detailed descriptions of this primary product and grouped them into one of five categories; Therapeutics, Diagnostics, Prognostics, Platforms & Tools and Services. Section 3 incorporated basic investment & financial information as well as assessing the currently intended customer type. The penultimate section 4 drew directly from Triple Chasm Company's navigator tool, presenting 36 questions to evaluate the execution of the twelve vectors by the venture. The survey then culminated with an opportunity for the submitter to provide their views on what the most useful interventions would be to help support their venture.

Incentives to provide this data included benefits provided by partner organisations, access to the following workshops informed by the collected data and an automated analysis that assessed the company's meso-economic vector performance against the benchmark scores for their current CRL. Care was taken to ensure submitted data was protected and anonymised as agreed in the Research & Development Society's privacy policy.



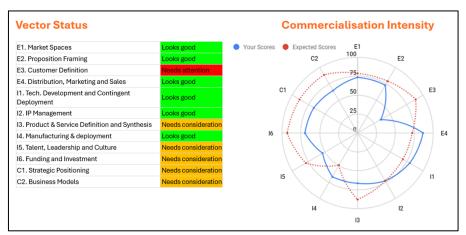


Fig 4. Example Response Output from RDS Life Science Ecosystem Mapper

We combined data collected from survey submissions with existing data, from the past 4 years, provided by the Triple Chasm Company. A dataset of over 170 products and services at different maturities, business models and product types provided a reasonable basis to develop our initial conclusions before testing them with stakeholders at each of our workshops. The geographic distribution showed coverage across most regions of the UK, although there are significant gaps and the "Golden Triangle" and Kent are overrepresented due to bias in the Triple Chasm Company's data and the varying success of the RDS' distribution partners.

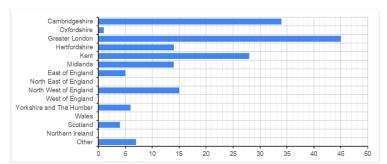


Fig 5. Geographic Distribution of RDS Life Science Dataset

The initial analysis evaluated the maturity distribution of the full dataset, grouping the products/services by their CRL. A complete population should show a monotonically decreasing chart but bias in data collection resulted in significant underrepresentation of ventures at CRL 0-2. The first key observation is that the majority of ventures have not yet crossed Chasm II, meaning that most companies do not yet have a viable business model. It is also notable that there are two major drops as CRL increases, between CRL 3 & 4 and between CRL 7 & 8. The drop across Chasm I is to be expected but curiously the second drop occurs after Chasm II. The most likely explanation for this is the case that many of the ventures positioned at CRL 7, will find their current business model is not viable with charter customers and they will need to reset and cross Chasm II again. This is a common occurrence across all sectors with most ventures crossing Chasm II several times before they identify a business model that proves viable in the long-term.



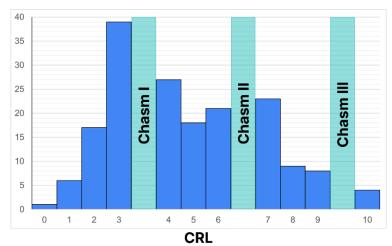


Fig 6. CRL Distribution

Investigating the vector profiles of companies at each CRL allows for a more nuanced understanding through comparisons of the average scores with benchmark values and each other. At the earliest maturities the impact of subjective bias can be observed most strongly, as young innovators often have little awareness of the broader challenges outside of the technical realm. Therefore, it is not surprising that the average scores at CRL 3 are above the benchmark across every vector except I1 (Technology Development & Contingent Deployment) and I2 (IP Management), where we can expect young innovators to be most familiar. The post Chasm I profiles at CRL 4 show little difference in terms of the average scores submitted but the benchmark scores indicate how E2 (Proposition Framing) and I6 (Funding & Investment) are now more significant and surpass the average self-assessment values.

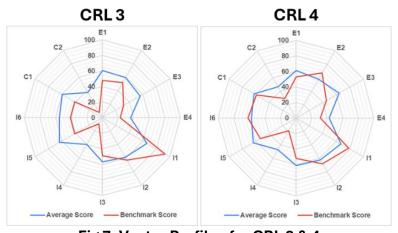


Fig 7. Vector Profiles for CRL 3 & 4

Companies managing Chasm II begin to face challenges hitting the benchmark scores across most vectors. Technology development at this point becomes a lesser concern as priorities must shift towards I3 (Product & Service Definition and Synthesis). The external and composite vectors also become increasingly important. At CRL 7 companies are falling short of the benchmark scores across every vector with the exception of technology development and IP management, indicating the scale of the challenge at Chasm II. Given the drop between CRL 7 & 8 it is worth comparing the



average scores between the two levels. While the average scores at CRL 8 were generally higher than at CRL 7, the most significant increases were found in vectors E4 (Manufacturing & Deployment) and I4 (Distribution, Marketing & Sales). These vectors are often neglected in the early stages of development of a new company but successfully incorporating these factors into a business model can be a deciding factor in successfully and permanently crossing Chasm II.

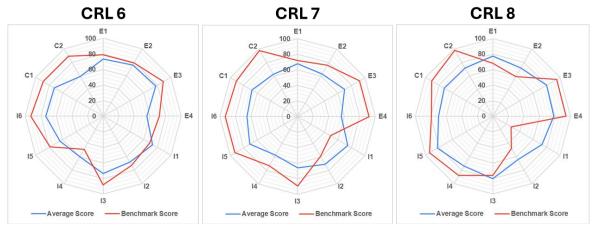


Fig 8. Vector Profiles for CRL 6, 7 & 8

Given the importance of accounting for domain specifics in our analysis, we developed a market-space centric value chain for the Life Sciences sector. This maps out the key value adding elements from early research to after care delivery. This value chain includes the traditional aspects of the sector as well as the new innovations driving the emergent market.

Lif	Life Sciences Research and Development					Pre-clinical Testing			Clinical Testing			Healthcare Interventions						Preventative Healthcare			Conventional Healthcare Delivery			Extended Care
Genes++	Proteins	Cells	Tissues & Structures	Organs & Systems	Whole Body	Pharmaco-dynamics	Pharmaco-kinetics	Toxicology Testing	Phase 1 Safety	Phase 2 Safety & Efficacy	Phase 3 Approvals	Metrology	Diagnostics	Therapies	Manufacture	Distribution	Delivery	Lifestyle	Wellness	Vaccination	Primary Healthcare	Secondary Healthcare	Tertiary Healthcare	Care in the Community

Fig 9. Market Space-centric Value Chain for Life Sciences

Through self-reported assessments from the survey and manual evaluations of Triple Chasm Company data points, a distribution of the different product types was produced. This showed that there is a relatively even spread of product types within the UK. Prognostics were the only category found to be underrepresented which may be due to the recency of innovations making use of this technology. Product type taxonomies often suffer from ambiguity at the margins and so we took care to carefully define each category. Therapeutics were defined as products that either directly



administer treatments or form constituent components of treatments. Diagnostics were defined as products that identify pathogens or ailments. Prognostics were defined as products that provide information to inform prognoses. Platforms & Tools were defined as generalised products for data collection, analysis and interpretation. Finally, services were defined as propositions where no physical or digital product is provided and instead revenue is obtained from direct use of a team's time & expertise. These categories were selected prioritising use-case rather than form, meaning that they do not distinguish between physical or digital products.

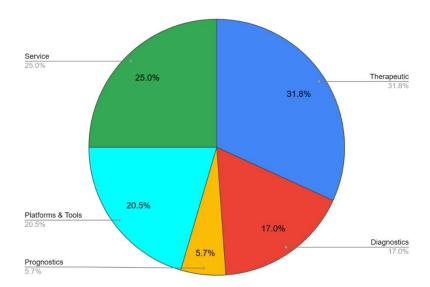


Fig 10. Product Type Distribution

Overlaying the product type taxonomy with the CRL distribution reveals distinct trends across different product types. Therapeutic and Prognostic focused ventures are struggling to reach Chasm II. Service focused ventures, however, have been very successful. Companies focused on Diagnostics and Platforms & Tools appear to have a relatively even distribution by comparison.

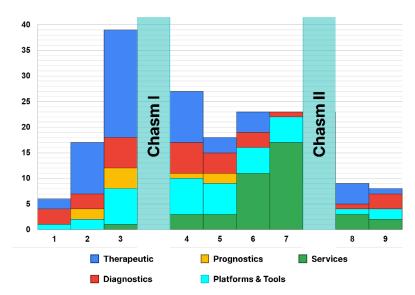


Fig 11. Product Type overlayed on CRL Distribution



Views on the most impactful interventions were only collected from survey respondents and thus make up a smaller sample size. Increased investment was almost universally considered the most significant of the proposed solutions, with a relatively even split found among the other options. It is notable that improved access to supplier networks is the lowest prioritised, especially given the significance of vectors E4 (Manufacturing & Deployment) and I4 (Distribution, Marketing & Sales) to Chasm II. The option to submit alternative solutions was also available and while few submissions made use of this, geopolitical factors were noted repeatedly. Uncertainty of UK-US trade relations and a lack of competitiveness with other international markets were both mentioned.

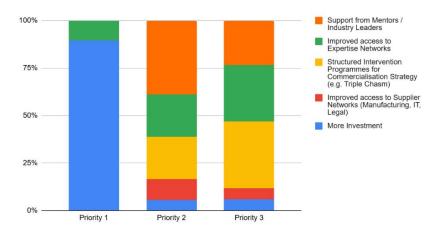


Fig 12. Perceived Most Impactful Solutions

Incorporating some of the financial data collected by the survey with existing Triple Chasm Company data allowed different investment types to also be mapped against maturity. The distribution shows an increasing share of financing from customers and decreasing share from informal sources over time as expected. It also shows that private investment like venture capital and angels account for less of a share than state agencies until after Chasm II at which point most ventures have already proven their business model is successful.

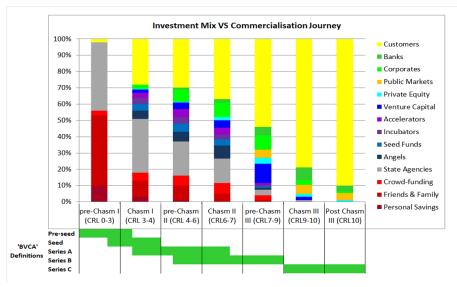


Fig 13. Investment Mix vs Maturity