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## From Idea to Therapeutic: Is There a Role for Developing a Regulatory Pathway Tool for Early Stage Research?

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# From idea to therapeutic – Is there a role for developing a regulatory pathway tool for early stage research?

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## Abstract

Academic institutions are a well-established source of pharmaceutical innovation. However, the researchers behind these discoveries are rarely responsible for successful translation of their findings to the market. It is hypothesized that by enhancing their understanding and knowledge of the regulatory requirements associated with drug development, the speed of innovation to market would be increased, while simultaneously decreasing technology transfer issues that arise as commercially focused projects move from academia to industry. The usefulness of an associated regulatory readiness tool to guide researchers involved in commercially focused projects will also be investigated.

**Key words:** Regulatory requirements; academia; translation; commercialisation

## 1. Introduction

The laboratory benches of academic institutions are a well-established source of pharmaceutical innovation, with many of the advancements made in modern medicine attributable to the basic scientific research carried out in these settings (Silber, 2010; Stevens *et al.*, 2011). The potential patient impact and wider societal benefits of the discoveries made in academic settings cannot be overstated. However, while central to the discovery and development of innovative therapeutic agents, academics and researchers are often not involved in the later stages of the drug development pathway, that ultimately sees their discovery brought to the market (Silber, 2010; Starokozhko *et al.*, 2020). Their expertise and interest is considered to lie in the scientific realm of the drug development pathway, as distinct from later stages associated with the commercialisation of the associated drug product (Collins *et al.*, 2016; Greene *et al.*, 2019).

Translating academic discoveries into safe and effective medicinal products is a long and arduous journey spanning, on average, twelve years and incurring significant financial costs,

estimated to be in excess of \$1 billion (Hudson *et al.*, 2013; Van Norman, 2016). There are no guarantees that, even after significant investment of time, money, and effort, that products will successfully emerge from the drug development pipeline (Greene *et al.*, 2019; Seyhan, 2019). Given the complexity of commercialising scientific research, it is little wonder that researchers and academics often take a narrowly-focused approach to their research, concentrating their efforts on solving the immediate scientific challenges of their discoveries rather than looking at a longer term approach to translating this research into a therapeutic for patients (Executive Office of the President of the United States, 2012; Collins *et al.*, 2016; Greene *et al.*, 2019).

The path from the lab to the receipt of a marketing authorisation is a challenging one which encompasses the “Valley of Death” representing the chasm between basic scientific research and successful commercialisation of a product (Seyhan, 2019). One result of this valley is that the academic discoveries are not having the anticipated impact on the market and in clinical settings. Despite the high number of novel therapeutic innovations emerging from academic institutions, there has not been a corresponding increase in the number of new, effective therapeutic agents available to treat patients (Freeman *et al.*, 2011; van Dongen *et al.*, 2013; Palmer *et al.*, 2017; Seyhan, 2019). There are countless reasons why academic discoveries can fall victim to this valley including cost constraints, lack of infrastructure in universities to support academics with commercialisation, and navigating the complexities of the regulatory requirements associated with commercialisation of scientific research (Hait, 2005; Homer-Vanniasinkam *et al.*, 2012; van Dongen *et al.*, 2013; Sanami *et al.*, 2017; Scannell *et al.*, 2019).

The complex regulatory environment is frequently cited in the literature as one barrier to translation of scientific research, with Hait (2005) postulating that this environment is “intimidating to even the most seasoned translational investigator” (Nagpal *et al.*, 2017; Sanami *et al.*, 2017; Scannell *et al.*, 2019; Starokozhko *et al.*, 2020). Scannell *et al.*, (2019) identify that regulatory knowledge is a “key knowledge deficit” among academics involved in commercially focused medical device projects. The European Commission has also cited a “lack of specific relevant know-how in regulatory science” as a key cause of issues with translation of scientific research (European Commission, 2020). It is with this in mind that an EU wide initiative known as STARS (Strengthening Training of Academia in Regulatory Science)

was launched in 2019, with a mandate to increase the awareness of academics to the regulatory environment (Starokozhko *et al.*, 2020). The former European Medicines Agency Executive Director Guido Rasi states that “Interaction with EU regulators and a better understanding of the regulatory environment can help academia translate their discoveries into patient-focused medicines” (Moulon, 2016). It is believed that early engagement with, and consideration of, the regulatory requirements associated commercialisation of scientific research can increase the likelihood of success of commercially focused academic projects (Starokozhko *et al.*, 2020).

It is interesting to note that funding calls by agencies including the European Commission’s Horizon 2020, Enterprise Ireland and the Innovation Medicines Initiative, recognise that successful applications will be required to consider regulatory issues as part of commercialisation strategies. For example Enterprise Ireland’s Commercialisation Fund applications require that “regulatory, reimbursement and other adoption barriers (are) explored and thought through”, indicating that failure to consider regulatory requirements of commercially focused projects can lead to unsuccessful funding applications (McShane, 2019). It becomes clear that engaging with the regulatory aspects of commercial projects is in the interest of the researcher, both from a funding perspective, and if they aspire to see their innovative discoveries reach the patient bedside.

With increasing focus in universities on the commercialisation of research in recent years, researchers must now embrace the commercialisation requirements associated with bringing their novel therapeutics from the laboratory bench to the market, including the regulatory requirements (Mehta, 2004; van Dongen *et al.*, 2013; Sanami *et al.*, 2017). With this in mind, and with the backdrop of the EU STARS initiative, this paper aims to gauge the awareness and knowledge of early stage researchers, academics, and Principal Investigators of the regulatory requirements associated with commercialisation of academic research. It is hypothesized that by enhancing their understanding and knowledge of the regulatory requirements, and encouraging early engagement with the regulatory aspects of commercially focused projects, speed to market could be increased, while simultaneously decreasing technology transfer issues that can arise as projects move from academia to industry.

In addition, this research will aim to determine if there is support for a regulatory pathway tool to help guide commercially-focused academic projects. The proposed tool would be similar to, and complement the widely utilised Technology Readiness Level (TRL) tool. Developed by NASA in the 1970's, the TRL tool categorises and defines, on a nine-point scale, the level of maturity or "readiness" of technologies in various stages of development. The TRL tool allows for effective communication and clear demonstration of the development status of different technologies (Héder, 2017).

Such is the usefulness of the TRL tool that it was embraced by numerous other organisations including the US Department of Defence and the European Space Agency. It has since been adopted as an innovation policy tool in the European Union. In 2014, TRLs were incorporated into the EU Commission Work Programmes for projects seeking funding as part of the Horizon 2020 programme for Research and Innovation (Héder, 2017). The European Commission definition of TRLs are summarised in Figure 1. (European Commission, 2014):

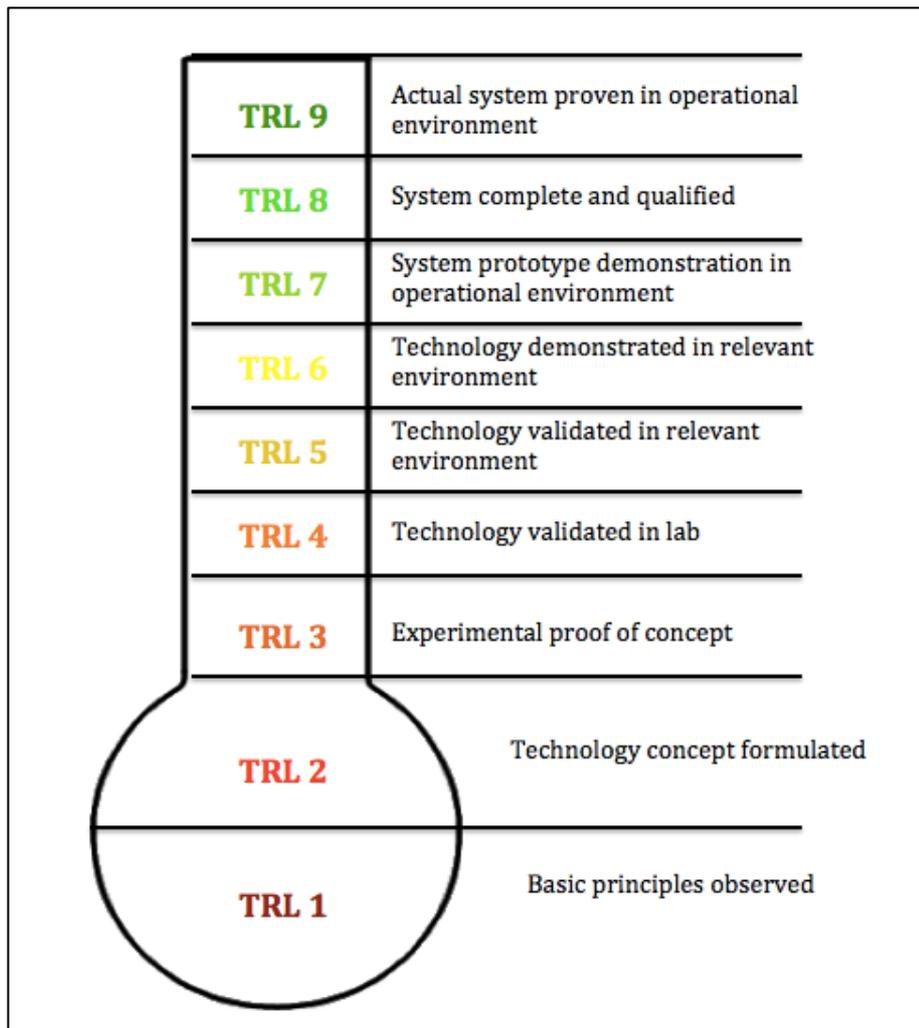


Figure 1: EU Commission TRL definitions

Given the usefulness of the TRL tool in the determination of maturity and readiness of technologies, this paper seeks to establish if there would be an appetite for a companion Regulatory Readiness Level (RRL) tool, which is currently under development by a member of the Pharmaceutical Regulatory Science Team in TU Dublin ([www.PRST.ie](http://www.PRST.ie)), for use by researchers and academics in university settings. The proposed RRL tool would have nine levels, with each of the nine RRLs corresponding to the associated TRL. The RRL will provide granular detail at these nine levels as to what is required from a regulatory perspective to progress from a corresponding TRL to the next. . Where the TRL tool determines maturity of the technology at each readiness level, the RRL tool would determine the readiness of said technology with respect to the associated regulatory requirements. A detailed description of the RRL is available in a separate article in this Journal (McGowran, 2020)

It is anticipated that the RRL tool would act as a guide for academics for what is required from a regulatory perspective at each readiness level, allowing them to align with the regulatory requirements at the associated readiness level. It would also act as a way to measure the preparedness of their technology from a regulatory perspective. (McGowran, 2020).

## **2. Aims and objectives of this paper**

- To establish the level of understanding and awareness of the regulatory environment amongst Early Stage Researchers, Academics, and Principal Investigators.
- To investigate if there is support for a Regulatory Readiness Level tool to help guide commercially focused projects.

## **3. Methodology**

Interviews with Subject Matter Experts (SMEs) and a survey of early stage researchers, academics, and Principal Investigators were carried out to meet the aims and objectives of this paper.

### **3.1 Interviews with SMEs:**

A total of six semi-structured interviews were carried out with SMEs from a number of Higher Education Institutions in Ireland in an effort to gain an insight into the perceived understanding and awareness of early stage researchers and academics of the regulatory requirements associated with commercialisation of pharmaceutical products and medical devices. The perspective of these six SMEs, namely Technology Transfer and commercialisation experts in a number of Irish Universities, regulatory consultants, and researchers with experience in commercialising scientific research were gathered during the course of the interviews.

### **3.2 Survey of Early Stage Researchers, Academics, and Principal Investigators:**

It was determined that a survey would be the most appropriate method to employ to gather the opinions of multiple early stage researchers, academics, and Principal Investigators involved in commercially focused projects. The survey was distributed online to researchers active in developing pharmaceuticals, biopharmaceuticals and medical devices in Ireland.

## 4. Research Outputs

### 4.1 Interviews with SMEs:

There were a number of common themes that were identified in the interviews carried out with SMEs. These included the impact that a lack of understanding and training of researchers on the regulatory requirements has on commercially focused projects; lack of foresight of researchers; the link between prior experience of researchers with regulatory requirements and confidence to engage in the regulatory process; failure of a project is not solely linked to a lack of regulatory readiness; lack of resources available to assist researchers with regulatory considerations; benefits to be gained as a result of early engagement with regulatory requirements; perceived usefulness of the proposed RRL tool; requirement for education of researchers in regulatory requirements and importance of engaging with same.

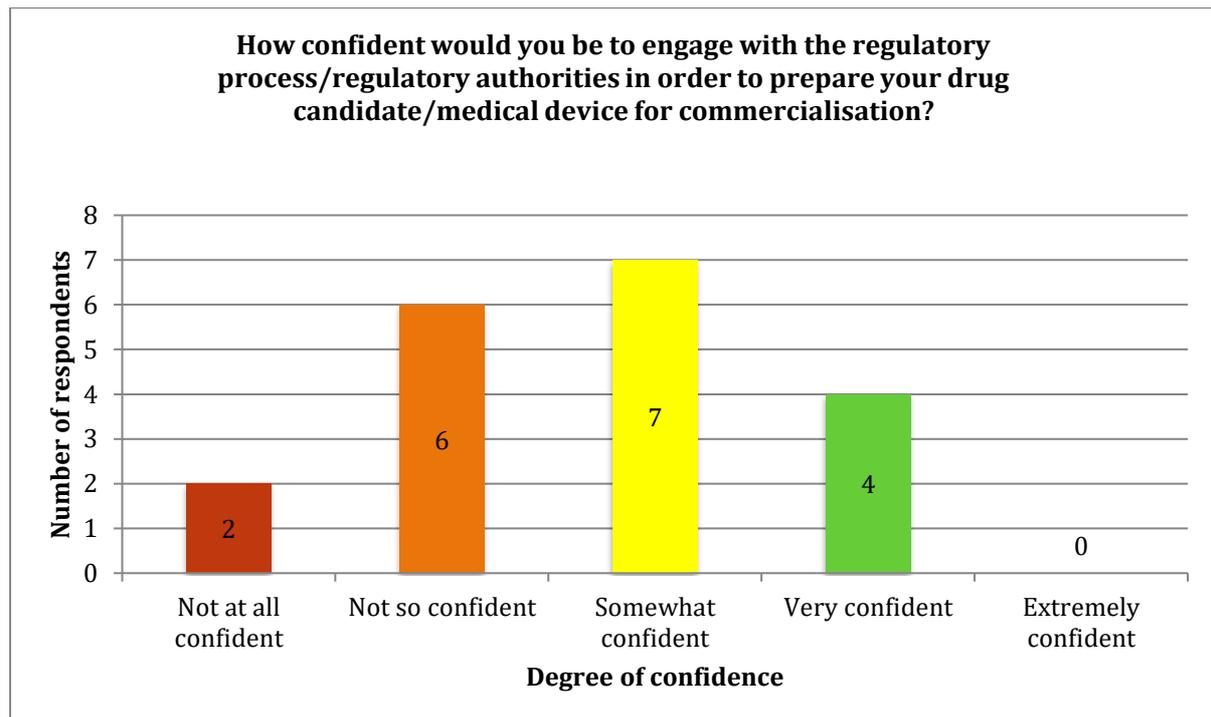
### 4.2 Survey of Early Stage researchers, Academics, and Principal Investigators:

A total of 19 responses were gathered to the survey issued to early stage researchers, academics, and Principal Investigators, with the breakdown of respondents as follows: Eight Principal Investigators, six early stage researchers, three academics, and two respondents selected the "other" category, identifying themselves as a project manager and a grant writer.

Initial questions aimed to establish if respondents believe it is important for them to give consideration to the regulatory requirements associated with commercialisation of their scientific research, and if respondents have any previous experience engaging with the regulatory pathway associated with commercialisation of scientific research. All respondents agreed that it is important for them to consider the regulatory requirements associated with their research. 74% of respondents (14/19) indicated that they had some exposure to the regulatory pathway associated with bringing scientific research to the market.

When asked whether there was any focus on regulatory science aspects of commercialisation of a product provided during training of researchers and academics involved in commercially focused projects, 58% (11/19) responded that there was a focus on regulatory science provided during their training.

Respondents were asked how confident they would feel to engage with the regulatory process and regulatory authorities in order to prepare their drug candidate/medical device for commercialisation. No respondents reported feeling extremely confident to engage in the regulatory process. Responses ranged from “not at all confident” (10%) to “Very confident” (21%). Approximately the same number of respondents reported feeling “not so confident” (32%) and “somewhat confident” (37%) to engage with the regulatory requirements associated with commercialisation of their research.



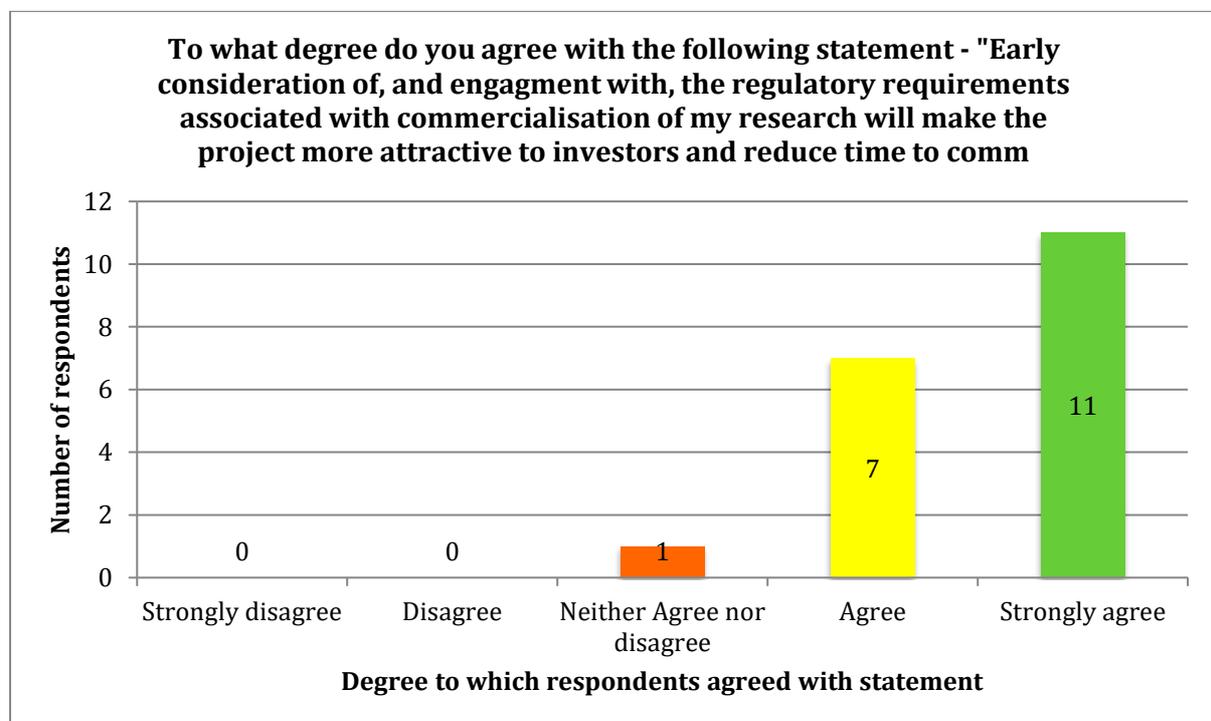
**Figure 2: Confidence of respondents to engage with regulatory process**

Barriers preventing their engagement with the regulatory requirements associated with commercialisation of their research were identified as follows: Complexity of requirements, lack of knowledge, difficulty in understanding requirements, time constraints, lack of focus of researchers on regulatory requirements-sole focus on scientific research, lack of infrastructure in universities to support researchers with regulatory requirements, lack of funding, high costs associated with contacting out regulatory considerations to experts.

Respondents recognised that there are benefits to early consideration of the regulatory requirements by researchers and these included: Less waste (time, money, animals etc.), bring greater focus and clarity to the project, avoidance of rework and revisions, higher

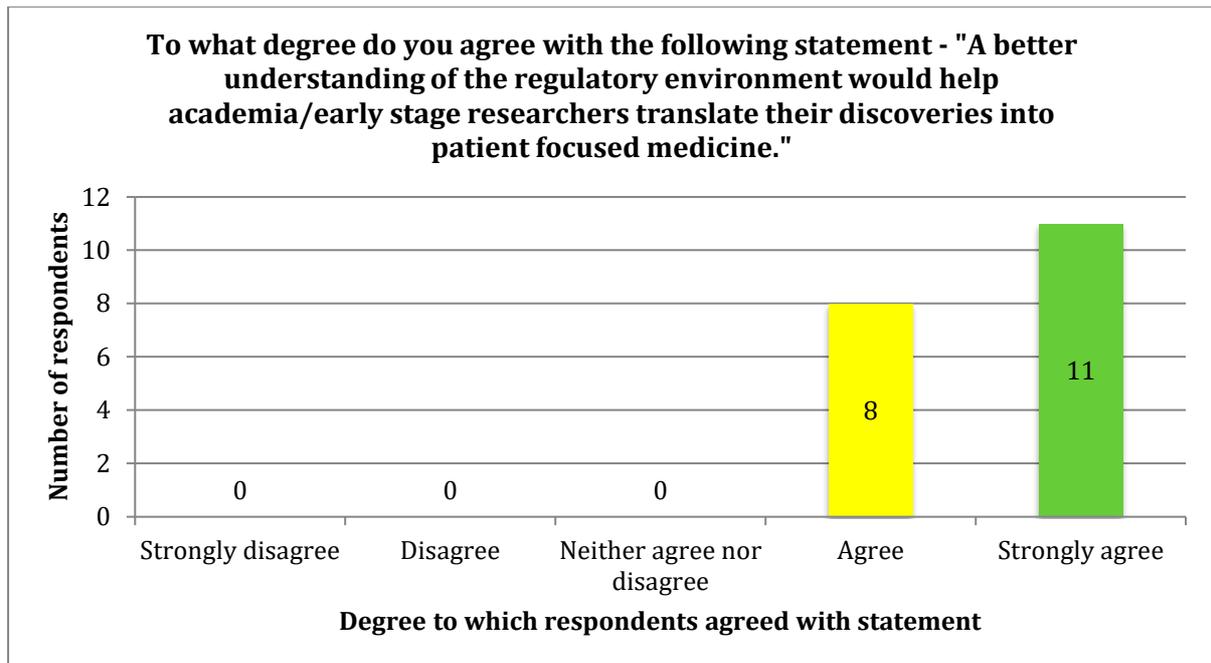
chance of successful translation of research to the market, encourage researchers to look at the “bigger picture” and the potential patient impact of their research.

A Likert scale was presented to respondents to gauge the degree to which they agree with the following statement, “Early consideration of, and engagement with, the regulatory requirements associated with commercialisation of my research will make the project more attractive to investors and reduce the time to commercialisation.”(Joshi *et al.*, 2015) No respondents disagreed with the statement. 1 respondent was neutral, selecting “neither agree nor disagree”, with the remaining 18 respondents agreeing with the statement to varying degrees. 37% (7/19) agreed with the statement, while 58% (11/19) strongly agreed.



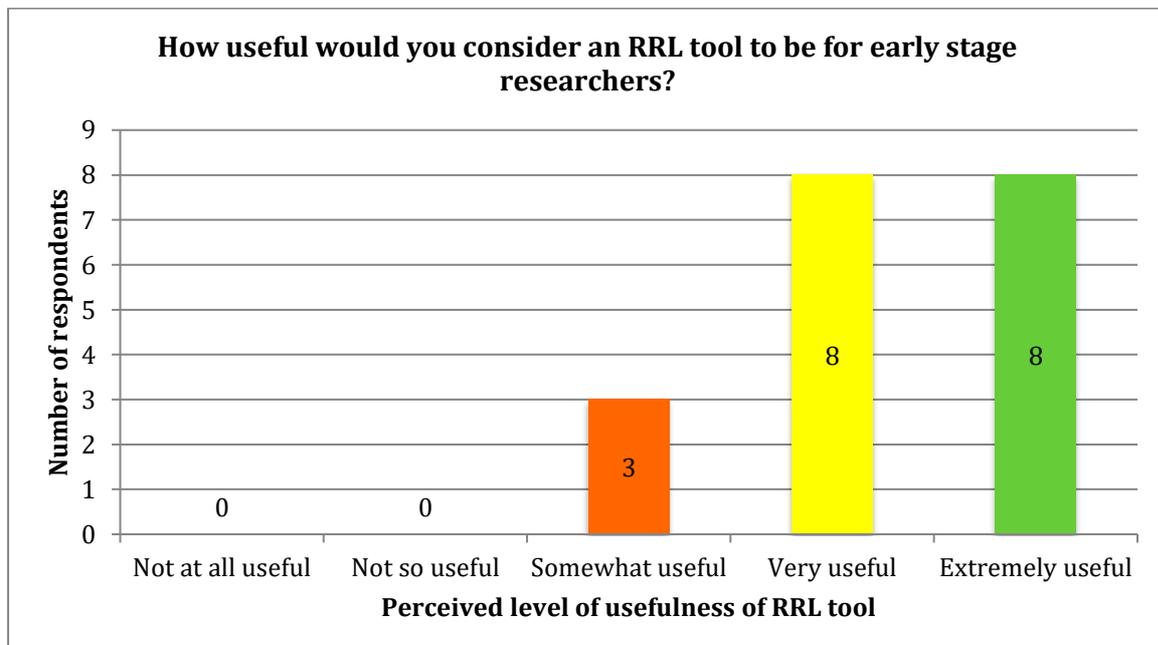
**Figure 3: Degree to which respondents agree that early consideration of regulatory requirements will make projects more attractive to investors and reduce time to commercialisation**

Additionally the following comment was provided - “ A better understanding of the regulatory environment would help academia/early stage researchers translate their discoveries into patient focused medicine”, and respondents were once again asked to what degree they agreed with the statement. All respondents agreed with the statement, with 42% (8/19) stating they agree, and the remaining 58% (11/19) stating they strongly agree.



**Figure 4: Degree to which respondents agree that having a better understanding of the regulatory requirements would help them to translate their discoveries into patient focused medicines**

Finally, the concept of the RRL tool was introduced and respondents were asked how useful they would consider such a tool to be to them. All agreed, to some degree, that this tool would be useful. Equal numbers believed that such a tool would be very useful or extremely useful (8/19 in both incidences). 16% (3/19) believed the tool would be somewhat useful.



**Figure 5: Perceived usefulness of the proposed RRL tool**

## 5. Discussion

### 5.1 Impact of the lack of understanding and training of researchers on the regulatory requirements:

Interviewees agreed that generally, academics and researchers do not have the requisite training, knowledge, or experience to effectively engage in the regulatory pathway associated with commercialisation of their scientific research. It was noted that the researchers have little exposure to the regulatory pathway and often rely on the expertise of external regulatory consultants to address the regulatory requirements and the associated nuances of the regulatory pathway. Requirement for external assistance also has additional repercussions for commercially focused projects; failure to consider regulatory requirements until such time as consultants are brought into the project results in lost time and the requirement for remediation work to be carried out to bring the project to the correct point with respect to the regulatory requirements. As a result, progress of projects is slowed when consideration is not given to the regulatory requirements. The cost associated with bringing regulatory experts into a project is also noted to be high.

### 5.2 Lack of foresight of researchers:

With some early academic discoveries, there may have been no commercial intent at the outset. Researchers will not recognise the commercialisable nature of their findings until they are at the "Proof of Concept" stage i.e. at TRL 3. Researchers will often only then begin to build a commercialisation roadmap and seek funding once they confirm that they have proof of concept. Therefore, regulatory requirements are only considered post this stage. This can lead to the requirement for remediation work to bring projects to the correct point with respect to the previously unconsidered regulatory requirements.

### 5.3 Link between prior experience of researchers with regulatory requirements and confidence to engage in the regulatory process:

They acknowledged that for those with no previous experience, engaging with the regulatory aspects of a project can be very daunting. SMEs report that researchers are fearful of the regulations and regulators, and their lack the basic knowledge pertaining to the regulations impedes them from effectively engaging with the process. However, if commercialisation of the technology is the ultimate goal, it is noted that researchers must become intimately familiar with the regulations, as this will determine if their technology is commercially viable

or not. If researchers cannot meet legislative standards, the product that arises from their research will not become a commercially viable product. If researchers want to commercialise their research, they should not be afraid of the legislation, but rather should be embracing it.

#### **5.4 Failure of a project is not solely linked to the lack of regulatory readiness:**

All interviewees were asked if they had been involved in a project that had failed as a result of a lack of consideration given to regulatory requirements or lack of “regulatory readiness”. All respondents concluded that it is not regulatory readiness alone that leads to failure of projects, but it can be a contributing factor. Lack of consideration of the regulatory requirements associated with commercialisation of scientific research can significantly delay a project, preventing advancement until regulatory requirements are remediated, and can also contribute to unsuccessful funding applications. It can also make projects less attractive to potential investors.

#### **5.5 Lack of resources available to assist with regulatory considerations:**

The SMEs interviewed highlighted that there are good supports in place to assist researchers with various aspects of commercialisation of their research, for example management of Intellectual Property. However, they note that there are no specific supports in place in universities to aid researchers with the regulatory aspects of such projects.

A number of the SMEs explain that while funding is available to progress research on the path to commercialisation, the amount is finite and often does not extend to cover the costs associated with the regulatory pathway. In one SME’s opinion, funding “never goes far enough, which means you don’t have the resources to bring in the required expertise.” It is interesting to consider the usefulness of the RRL tool in light of this finding, as if there are insufficient funds available to engage regulatory consultants, having a tool to guide researchers through the regulatory pathway, would be very beneficial, both in terms of time and cost savings.

#### **5.6 Benefits of early engagement with regulatory requirements by researchers:**

The researcher was eager to understand if the SMEs believed that increasing the awareness of early stage researchers to the regulatory requirements would increase the speed of commercialisation and decrease the number of drugs lost to the Valley of Death.

Interviewees all agreed that the speed of commercialisation could be increased and enhanced if researchers had a greater awareness and understanding of the regulatory requirements applicable to their stage of research. All SMEs agreed that research projects that give consideration to regulatory requirements and have a plan in place to address same early in the timeline of the project, will become instantly more attractive to investors. Building in the regulatory pathway and demonstrating to investors that not alone has the project demonstrated proof of concept and has a commercialisation roadmap in place, but has also benchmarked the project against the regulatory standards will impress potential investors.

With respect to decreasing the number of drugs lost to the Valley of Death, interviewees all concluded that early stage therapeutic projects tend to be lost as a result of issues relating to funding, more so than as a direct result of issues relating to the regulatory readiness of the research. If financial support of the project is limited, it is unlikely that there are any supplemental funds available to spend on regulatory consultants. If researchers had a greater understanding of the requirements and did not require external assistance, which comes at a high price, this would be beneficial to the project as a whole.

#### **5.7 Perceived usefulness of the proposed RRL tool:**

When asked if they believed an RRL tool would be useful, SMEs were all in agreement that it would be a very useful tool to guide early stage researchers along the regulatory pathway.

Having a recognised tool that lays out the pathway and requirements to coincide with their research timelines would be very useful for researchers. Such a tool would provide a roadmap to researchers who have little to no understanding of the requirements and guide them through the process. It was noted that the introduction of such a tool would be timely, with interest in academic and university settings in commercialising research increasing in recent years. SMEs were keen to stress that such a tool must be simple to use and not dissuade researchers from engaging with the regulatory aspects of a project.

One SME, a researcher with experience in commercialisation, raised an interesting point regarding the usefulness of the RRL tool for early stage researchers that links to the issue that arises as a result of a lack of foresight of researchers. If the researcher is working towards

commercialisation from the outset, he agrees that a companion regulatory framework tool would be massively beneficial. However, if the researcher is engaging in “blue sky research” and does not recognise the commercial potential of their discoveries for some time, it is less likely that they will engage with an RRL tool at this early stage. If they are solely focused on their research and subsequently provided with reams of documents pertaining to regulatory requirements, they will feel this is not relevant to them or their research and will not engage. Perhaps if the seed of commercialisation potential of scientific research was sown from an early stage, and the benefits of considering the regulatory requirements that would be applicable at say TRL 1,2, and 3 were highlighted, early stage researchers may be more likely to engage.

One SME noted that researchers and academics are very familiar with the TRL concept and associated language and thus, this would help researchers understand the standing of their technology with respect to the regulatory requirements. The proposed alignment of the RRL tool with the TRL concept was well received.

#### **5.8 Requirement for education of researchers with respect to regulatory requirements:**

It was noted by interviewees that for early stage researchers and academics, a degree of “buy-in” will need to be fostered in order to impress upon researchers the importance of, and benefits of, their early engagement with the regulatory aspects of their project. As this is not something that is currently within their remit, without education pertaining to its importance, there may be some resistance. Researchers must be educated to understand that making their asset more commercialisable (through, for example, considering regulatory requirements at an early stage) ultimately increases the value of their opportunity.

#### **5.9 Survey of early stage researchers, academics, and Principal Investigators:**

With 100% of respondents agreeing that it is important for them to give consideration to the regulatory requirements associated with their scientific research, it is clear that awareness of said requirements among this cohort is high. The majority of respondents also recognised the benefits that engagement with the regulatory requirements will confer on a project. What is interesting to note is that this awareness is not matched with a high level of confidence to engage with the regulatory aspects of their projects. Equally, having previous experience navigating the regulatory pathway associated with commercialisation of research did not

result in a significant increase in confidence of researchers to engage; of the 14 respondents who reported having previous experience engaging with the regulatory requirements, only 4 reported feeling very confident to engage with the regulatory process in order to prepare their scientific research for commercialisation. The remaining 10 respondents reported that they would feel “not so confident” (3/14) and “somewhat confident” (7/14). The high level of awareness does not result in an increased likelihood or confidence to engage with the regulatory aspects of a project.

The barriers to engagement with regulatory aspects of commercially focused projects noted by researchers were aligned with those identified by the SMEs. The most frequently cited barrier was lack of knowledge and understanding of the complex and difficult to interpret regulations. This is followed closely by lack of funding and high costs associated with bringing regulatory consultants into the project. The proposed RRL tool has the potential to help researchers circumnavigate these barriers by providing a clear pathway, detailing the exact regulatory requirements as the project progresses.

Again, the benefits of early engagement with the regulatory requirements identified by researchers coincided with those expressed by SMEs. Efficiency, avoidance of revision and rework, optimisation and refinement of the pathway to commercialisation, and time and cost saving in the long run were the most frequently cited benefits.

Recognition that early familiarity with the regulatory requirements will make projects more attractive to investors and will reduce time to commercialisation was high among researchers, corroborating the sentiments of SMEs. Researchers also generally agreed that having a better understanding of the regulatory requirements will help them to translate their discoveries into patient focused medicine, echoing the sentiment of SMEs, and former EMA Executive Director Guido Rasi. This again confirms that the awareness of the importance of the regulatory requirements among researchers is high. While they may be reluctant to engage, it is clear that they have a good understanding and awareness of the potential benefits that could be gained should they they choose to actively engage with regulatory aspects of their scientific research.

What can be deduced from the above is that awareness of the regulatory requirements is not the key issue; knowledge and confidence to engage is. The positive reaction to the RRL tool also further highlights that researchers would likely engage in the process themselves if there was a support tool available to guide and direct them.

### 5.10 Comparison of Opinions of SMEs and Researchers elucidated through interviews and surveys respectively

When comparing responses from both SMEs and researchers, it was interesting to note that their opinions were not completely in alignment. Both cohorts identified similar barriers and benefits to early engagement of researchers with regulatory requirements, and also agreed that the proposed RRL tool would be beneficial for researchers. However, SMEs felt that researchers had little awareness of the regulatory requirements, do not recognise their importance, and have little to no formal training with respect to these requirements. This was not in line with the findings of the survey, where 100% of respondents agreed that it is important for researchers to give consideration to the regulatory requirements of their research, and 58% reported receiving training relating to regulatory science. SMEs believe significant education of researchers will be required in order to impress the importance of the regulatory aspects of their research upon them, however the results of the surveys of researchers indicate that their awareness of the importance of this aspect of their research is already high. The differences and similarities in the opinions of both parties are presented in table 1.

**Table 1: Comparison of opinions of SMEs and researchers elucidated through interviews and surveys respectively**

	Opinion of SMEs	Opinion of Researchers
Awareness of researchers of regulatory requirements	Low	High
Importance of regulations to researchers	Low	High
Training of researchers with respect to regulatory science	None	Some -58% of respondents report receiving training
Perceived barriers to engagement of researchers with regulatory aspects of their research	<ul style="list-style-type: none"> <li>• Lack of knowledge</li> <li>• Lack of funding</li> <li>• Lack of infrastructure to support regulatory aspects of projects</li> <li>• Complexity of requirements</li> <li>• Not experts in this area</li> </ul>	In line with SMEs opinions

	<ul style="list-style-type: none"> <li>• Not focused on commercial nature of discoveries</li> <li>• Fear of regulations and regulatory authorities</li> </ul>	
Perceived benefits to engagement of researchers with regulatory aspects of their research	<ul style="list-style-type: none"> <li>• Increased attractiveness of project to investors</li> <li>• Time saving in the long run</li> <li>• Clearer pathway to market</li> <li>• Higher chance of successful translation to the market</li> <li>• Increased speed of project to commercialisation</li> </ul>	In line with SMEs opinions
Usefulness of RRL tool	Very useful	Very useful

## 6. Future Work in this area

SMEs and researchers both cited a lack of knowledge of the regulatory environment as a barrier to the engagement of researchers with this aspect of drug development. Research into the current training pertaining to regulatory science, both at undergraduate and postgraduate level, could be investigated to determine if this identified gap is as significant as it appears in the findings of this research. It would be interesting to understand if incorporation of structured regulatory science training into undergraduate and postgraduate Life Science degree programs would increase the confidence of future researchers to engage with the regulations, and bridge the knowledge gap that is evident for current researchers.

The research for this paper was limited to an Irish context and it would be valuable to establish if this was mirrored in other countries.

Investigations into the differing opinions of SMEs and researchers could be examined in more detail to understand the reason for the apparent divergence in the opinions of both parties. For example, it would be interesting to determine why the SMEs interviewed believe that researchers have little awareness of regulatory requirements and their importance, despite

all survey respondents reporting high awareness and understanding of the importance of the regulatory requirements associated with their scientific research.

Most importantly, work on the development, validation, and implementation of the RRL tool in academic settings, followed by investigations into the real world application and usefulness of the RRL tool needs to be progressed.

## **7. Conclusions**

Through interviews with SMEs and a survey of early stage researchers, academics, and Principal Investigators, it is clear that while all stakeholders agree that it is important for researchers to give consideration to the regulatory requirements associated with commercialisation of scientific research, at present, researchers do not have the knowledge or expertise to fully and confidently engage in the process. The high level of awareness of researchers of the importance of early consideration of the regulatory aspects of their work and the acknowledgement and understanding of the benefits that will be conferred on a project through their engagement with same was encouraging.

A number of benefits to early consideration of, and engagement with, the regulatory requirements by researchers were confirmed throughout the course of this research. These include increased speed of a project to commercialisation, increased attractiveness of a project to potential investors, a clearer path to the market for basic scientific research, and reduced need for remediation with respect to regulatory requirements of commercially viable projects in later stages of development that may not have given early consideration to same.

The proposed RRL tool was well received by both SMEs and survey respondents, indicating that there would be support among stakeholders for a tool to guide researchers through the requirements of each stage of the regulatory pathway, thereby increasing their confidence to engage with the regulatory requirements associated with their research and discoveries. The barriers to engagement with regulatory aspects of commercially focused projects, namely complexity of the requirements and knowledge deficits of researchers in this regard, could potentially be overcome and ameliorated with the introduction and utilisation of the proposed RRL tool.

To conclude, the words of one of the SMEs interviewed for this research summarises the premise of this paper well: “An excellent academic who has a better understanding of the regulatory pathway, the timelines, and what is required, can only be a good thing.”

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