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ORIGINAL RESEARCH

Can a biobank network and supporting infrastructure enhance Ireland's ability to attract pharmaceutical research and development and clinical trial opportunities? A pilot survey

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Abstract: Ireland has an established reputation in specialized global pharmaceutical manufacturing. However, simple high-volume manufacturing will not sustain the Irish pharmaceutical industry, and government agencies recommend a greater focus on innovation and research and development (R&D). Biobank Ireland Trust sought the views of the Irish pharmaceutical industry on the potential benefits of a national biobank network (NBN), national biobank web portal (NBWP), and center for translational molecular oncologic pathology (CTOP). Questionnaires were sent to 19 companies and eleven responded. Questionnaire A was completed by six companies presently engaged in R&D in Ireland – three pharmaceutical companies, two spin outs, and one contract research organization. Six of six respondents reported that: a NBN would benefit their company; the development of a NBWP was important; and finally, they forecast that the requirement for biobanked material would continue to increase. While three of six predicted that a NBN would facilitate an expansion of current R&D activities. The relative importance of accessing biobanked material and data varied. An associated NBWP was considered essential to enable researchers to rapidly determine the content of the NBN for research, including preclinical studies. Individual companies had requirements for biobanked material from a wide variety of cancer sites, sample types, and sample derivatives. Questionnaire B was completed by five pharmaceutical companies currently not engaged in R&D in Ireland. Four of five reported that a CTOP would benefit their company. All five stated that a CTOP could cultivate industry–academic collaborations. All five also determined that NBN–NBWP–CTOP infrastructure would assist in promoting Ireland as an R&D center. Finally, four of five indicated that an NBN would make Ireland more competitive for new clinical trials. This pilot survey suggests that an NBN with associated infrastructure would greatly facilitate research conducted by the pharmaceutical sector in Ireland.

Keywords: pharmaceutical industry, Irish biobanks, NBN, CTOP, NBWP, biobanked material

Introduction

Ireland, as the location of choice for 8 of the top 10 pharmaceutical companies, and producer of 5 top 20 medicines, is an important manufacturing base for the world's pharmaceutical industry.[1–10] However, it is now recognized that simple high-volume manufacturing alone will not sustain the long-term future of pharmaceutical companies in Ireland. Government agencies recommend focusing on innovation and research and development (R&D) and developing formal processes to exploit the complementary

expertise in academia and industry.[11] Globally, fiscal consolidation, spiraling R&D costs, declining research pipelines, and the decline of blockbusters, ie drugs which generate in excess of 1 billion dollars per annum, are challenges currently facing the industry.[1–12] Ireland also faces specific challenges: it is one of the most costly countries in the Euro zone to do business, several drugs, manufactured in Ireland, went off patent in quick succession, and there is a need for a better mechanism for the integration of novel biomarkers into treatment plans for oncology patients.[9–12] Increasingly, patients receive specific targeted therapies for cancer, and anecdotal evidence would suggest that cohesive structures do not exist to expedite the integration of novel and emerging biomarker tests into the Irish health care system.

Traditionally, Irish biobanks have been utilized by researchers in academic institutions. Industry–academic collaborations have been limited, possibly attributable to a person-dependent culture.[12] The degree to which the industry has utilized biobanks is difficult to establish. Without a national catalog of biobanked material, it is also difficult to pinpoint the number of samples, at various institutions, which could potentially (with the correct consent) be made available to industry. Biobank Ireland Trust (BIT) was established to promote the development of a National Biobank Network (NBN). The network, which commenced in 2008, aims to deliver benefits for patients, researchers, industry, and the economy.[13,14] BIT engages with stakeholders, including patient advocate groups, who are positive about industry accessing their donated biobanked material (blood, tissue, etc), because of the hope of new and improved treatments. BIT's network, which is under development, could also act as an interface between industry and academia, to assist in fostering collaborations.

It is important that the network can facilitate both academic and industrial researchers, providing all projects are 1) ethically approved and 2) satisfy the criteria laid down in the Sample Access Policy.[14] Therefore, BIT sought to obtain an overview of R&D currently being undertaken by the Irish pharmaceutical industry, to identify industry-specific biobank requirements, and to determine whether a national biobank web portal (NBWP) or searchable online catalog of biobanked material and center for translational molecular oncologic pathology (CTOP) would add value to the network.

Methods

In June 2013, BIT hosted a meeting with representatives from industry. There were four objectives: 1) to enable BIT to gain a more comprehensive overview of the landscape of R&D within the Irish pharmaceutical industry, 2) to identify the biobanking requirements of industry in the next 1–5 years, 3) to increase visibility and keep industry abreast of recent NBN developments, and 4) to identify differences, if any, that exist between the biobanking needs of industry and academia.

The attendees included representatives from global pharmaceutical companies with affiliates in Ireland, one contract research organization and two spin-out companies, established to exploit intellectual property generated in higher education institutes.[15,16]

Although the generic requirements of industry were identified, the specific requirements of individual companies were not determined, possibly attributable to a reluctance to discuss the exact nature of future research in front of competitors. Following internal discussion, it was decided that follow-up questionnaires emailed privately to each company representative might prove more effective at determining the precise requirements of industry for a NBN and related infrastructure.

Two questionnaires were generated and submitted to 19 companies. Questionnaire A was developed for companies conducting R&D in Ireland, while Questionnaire B was for companies without a research footprint (Figures 1 and 2). Questionnaire A asked whether an NBN would benefit an individual company and cultivate further R&D opportunities, to evaluate the development of NBWP and to outline present and future biobank material requirements. Questionnaire B sought to determine whether a NBWP and CTOP linked to a NBN have the capacity to benefit industry, cultivate future industry–academic collaborations, and assist in promoting Ireland as a viable R&D center. Questionnaires were based on BIT's engagement with industry and feedback from the June 2013 meeting. Respondents' names and companies were pseudoanonymized to protect commercially sensitive information. Fionnuala Gibbons (Molecular Medicine Ireland) was instrumental in making BIT aware of a number of small to medium indigenous enterprises.

Results

Of the 19 companies, eleven (58%) completed the questionnaires. Replies were not received from the other companies, despite follow-up emails and phone calls.

Questionnaire A

Questionnaire A was completed by six companies presently engaged in R&D in Ireland – three pharmaceutical companies, two spin outs, and one contract research organization.

Question 1	**In your opinion, would the development of a national biobank network, to deliver ethically and legally compliant, quality controlled biobanked material (FFPE tissue, fresh frozen tissue, blood, etc) and associated data benefit your company?**		
Yes =6 of 6 (100%)	No =0 of 6 (0%)		
Additional comments			
Pharmaceutical company 2	Our company [is] required to obtain clinical specimens under strict IRB approval protocols with informed consent and the utmost attention to issues of patient safety, anonymity and confidentiality. Informed consent is required from all donors irrespective of the host country's current legislation. Compliance with FDA regulations and adherence to international ethical guidance		
Contract research organization	We regularly have need for biomarkers both for our own internal research and for that of our client companies. Sample sourcing is a highly important part of our business.		
Question 2	**In your opinion would the development of a national biobank network, as described in question 1, allow your company to expand its current R&D operation?**		
Yes =3 of 6 (50%)	No =3 of 6 (50%)		
Additional comments from respondents who answered yes			
Pharmaceutical company 2	Samples collected aligned with […] policies with the proper consenting process will allow [us] to expand our preclinical studies and validation		
Pharmaceutical company 3	[…] has emerging onc portfolio which will require network of supporting research structures		
Spin out 1	Access to ethically derived primary tissue would greatly improve our research efforts		
Additional comments from respondents who answered no			
Pharmaceutical company 1	Current oncology molecules under trial are at an early stage and analysis is conducted at […]		
Contract research organization	This would be a very useful resource for us, though local access to such a biobank would not specifically lead to an increase in our R&D		
Spin out 2	[…] is currently conducting preclinical animal work, but biobanked material will be of interest for future biomarker development		
Question 3	**In your opinion, do you perceive that the demand for biobanked material will increase in the next 5 years?**		
Yes =6 of 6 (100%)	No =0 of 6 (0%)		
If yes, please estimate the increase in %			
Pharmaceutical company 1	1 year =3%	1–3 years =5%	3–5 years =5–7%
Pharmaceutical company 2	1 year =10%	1–3 years =20%	3–5 years =30%
Additional comments	Working directly with a national biobank network that allow us to customize prospective collections will expand our research validation specifically on rare disease		
Pharmaceutical company 3	1 year =10%	1–3 years =10%	3–5 years =10%
Additional comments	Difficult to accurately estimate here		
Contract research organization	1 year =20%	1–3 years =20%	3–5 years =20%

Figure 1 (Continued)

Additional comments	We would see a growth across the entire industry in requirements for samples. These estimates are quite conservative		
Spin out 1	1 year =50%	1–3 years =70%	3–5 years =80%
Spin out 2	1 year =5%	1-3 years =10%	3-5 years =15%
Additional comments	A well curated and advertised biobank will likely increase the demand for the material within the biobank		
Question 4	**In your opinion, is the development of a national biobank web portal important?**		
Yes =6 of 6 (100%)		No =0 of 6 (0%)	
Additional comments			
Pharmaceutical company 2	[Yes. Would increase] effectiveness of internal communication and will improve productivity		
Contract research organization	The ability to determine the contents of the biobank in a simple and rapid manner would be highly beneficial for us		
Spin out 1	Knowledge of facilities and available assets would be essential		
Spin out 2	A web portal is an essential part of an accessible biobank		
Question 5	**Please rank the relative importance of accessing biobanked material and associated data to your company 1= important 5= unimportant**		
Important =3 of 6 (50%)		Unimportant =1 of 6 (17%)	
Pharmaceutical company 1	5		
Additional comments	The relative importance is based on current company activities at this point and is not a refection to [reflection of] the important work being done		
Pharmaceutical company 2	1		
Additional comments	High quality of human tissues associated with the donor clinical information and pathology reports with diagnosis confirmed are critical for […] studies
Pharmaceutical company 3	2
Contract research organization	1
Additional comments	Biomaterials are of critical importance to us for biomarker discovery, assay development and validation.
Spin out 1	1
Spin out 2	3
Question 6	**Please select the samples of interest to your company**
Tumor (5 of 6), healthy tissue (2 of 6), FFPE tissue (2 of 6), fresh frozen tissue (3 of 6), whole blood (5 of 6), serum (4 of 6), plasma (3 of 6), circulating tumor cells (3 of 6), cell free DNA samples (3 of 6)	
Contract research organization	Our most common needs are fresh and FFPE tissue (and ideally FF and FFPE pairs). As [we] are a service company, however, we get a wide range of requests from our pharma [pharmaceutical] partners for many different sample types.
Pharmaceutical company 3	Difficult to accurately foresee exact requirements at this point in time
Question 7	**Please select the cancer sites of interest to your company**
Colon (4 of 6), breast (5 of 6), prostate (2 of 6), melanoma (6 of 6), lung (4 of 6), gynae (3 of 6), lymphoma (4 of 6), pancreatic (4 of 6), liver (2 of 6), kidney (3 of 6)	
Question 8	**What additional cancer sites may be of interest in the next 3-5 years?**
Multiple myeloma (2 of 6), chronic lymphocytic leukaemia (1 of 6), non-small-cell lung cancer (1 of 6), mesothelioma of the lung (1 of 6), small cell carcinoma (1 of 6), AML (1 of 6), oesophagus (1 of 6), head and neck (1 of 6)	
Contract research organization	Any cancer that the pharma [pharmaceutical] industry is developing therapeutics for is a potential need for sample sourcing

Figure 1 Responses to questionnaire A for companies currently conducting R&D in Ireland.
Notes: Six companies (three Biopharmaceutical companies, two spin outs, and one contract research organization) responded. Company names are not provided but respondents' comments are reproduced in full. Where "[...]" occurs it refers to the omission of company names to protect respondents identity and participant confidentiality.
Abbreviations: AML, acute myeloid leukemia; FDA, US Food and Drug Administration; FFPE, formalin-fixed, paraffin-embedded; gynae, gynaecological cancers; IRB, Institutional Review Board; onc, oncology; R&D, research and development.

Question 1	**A center for translational molecular oncologic pathway (CTOP) will provide:** • **Pathology** • **Molecular pathology, and** • **Biomarker validation services** **Will the development of CTOP benefit your company?**
Yes =4 of 5 (80%)	No =1 of 5 (20%)
Additional comments from respondent who answered no	
Pharmaceutical company 4	There is unlikely to be any significant benefit in the short- to midterm as our company has only a limited participation in clinical trials in Ireland. I would not personally dispute the wider benefits to industry however
Additional comments from respondents who answered yes	
Pharmaceutical company 5	Yes, it would greatly assist efforts to establish Ireland as a center to conduct world class oncology research within the […] global organization. Ireland is currently not on […] geographical footprint, a situation we hope to rectify; development of the CTOP will certainly aid our efforts and increase our competitive advantage
Pharmaceutical company 6	Providing these resources and a unified approach mean that Ireland can become competitive for clinical studies, especially earlier phase studies
Pharmaceutical company 8	Yes, it would be wonderful to showcase this to […] global and could well assist us in continuing to attract new clinical trial opportunities into Ireland

Question 2	**In your opinion, does CTOP have the potential to cultivate future collaborations between the bio-pharmaceutical industry and hospital affiliated research groups?**
Yes =5 of 5 (100%)	No =0 of 5 (0%)
Additional comments	
Pharmaceutical company 6	While […] does not have R&D facilities here, it does support research through investigator sponsored research
Pharmaceutical company 8	Yes, definitely. Especially, if defined research partnerships can be identified and executed
Question 3	**Would a well established Irish biobank network linked to CTOP and including a biobank web portal assist in promoting Ireland as a viable R&D center within the European bio-pharmaceutical industry?**
Yes = 5 of 5 (100%)	No = 0 of 5 (0%)
Additional comments	
Pharmaceutical company 4	Although many companies have their own biobanking facilities and partnerships it would of course present Ireland as country that is serious about R&D [research and development]
Pharmaceutical company 6	Yes it would, again it would need to [be] aligned with ICORG and work seamlessly

Figure 2 (Continued)

Question 4	**In your opinion, would access to a functional Biobank Network aligned with clinical trials, significantly benefit your company?**
Yes =4 of 5 (80%)	No =1 of 5 (20%)
Additional comments from respondent who answered No	
Pharmaceutical company 4	Unlikely at present [,] see answer to question 2*
Additional comments from respondents who answered yes	
Pharmaceutical company 6	Especially in relation to biomarker analysis
Pharmaceutical company 8	We would like to try to identify a specific project with tangible outputs that would clearly demonstrate the value of a functional biobank network + clinical trials to […] global
Question 5	**What samples have previously proven useful during drug discovery and development within your bio-pharmaceutical company?**
Tumor (5 of 5), healthy tissue (1 of 5), FFPE tissue (5 of 5), fresh frozen tissue (2 of 5), whole blood (2 of 5), serum (2 of 5), plasma (2 of 5), circulating tumor cells (2 of 5), cell free DNA samples (1 of 5)	

Figure 2 Responses to questionnaire B for biopharmaceutical companies.
Notes: Five companies responded. Company names are not provided but respondents' comments are reproduced in full. *The authors note this respondent did not provide comments for question 2. Where "[...]" occurs it refers to the omission of company names to protect respondents identity and participant confidentiality.
Abbreviations: FFPE, formalin-fixed, paraffin-embedded; ICORG, All-Ireland Cooperative Oncology Research Group; R&D, research and development.

Six of six respondents reported that: a NBN would benefit their company; the development of a NBWP was important; and finally, they forecast that the requirement for biobanked material would continue to increase. While three of six predicted that a NBN would facilitate an expansion of current R&D activities. The relative importance of accessing biobanked material and data varied. An associated NBWP was considered essential to enable researchers to rapidly determine the content of the NBN for research, including preclinical studies. Individual companies had requirements for biobanked material from a wide variety of cancer sites, sample types, and sample derivatives. Results and respondent's comments are presented in Figure 1.

Questionnaire B

Questionnaire B was completed by five pharmaceutical companies currently not engaged in R&D in Ireland. Four of five reported that a CTOP would benefit their company. All five stated that a CTOP could cultivate industry–academic collaborations. All five also determined that NBN–NBWP–CTOP infrastructure would assist in promoting Ireland as a R&D center. Finally, four of five indicated that an NBN would make Ireland more competitive for new clinical trials.

Discussion

In this pilot survey of the Irish pharmaceutical sector, companies, whether engaged in R&D (Questionnaire A) or not (Questionnaire B), stated that NBN–NBWP–CTOP would benefit them. The companies predicted an increase in demand for biobanked material in the ensuing 5 years. NBN–NBWP–CTOP infrastructure could also assist in attracting new clinical trials, in promoting Ireland as a viable R&D center, and in cultivating novel industry–academic collaborations. Results cannot be compared with those of two previous studies because Ireland is not yet a member of Biobanking and Biomolecular Resources Research Infrastructure, and awaits both biobank legislation and a governing authority, as in the United Kingdom.[17–19] In contrast to industry, academic researchers, based on an unpublished survey of 44 researchers attending the Irish Society for Cancer Research Meeting in 2011, investigate only one or two cancer sites and require fewer and less varied sample types or derivatives (Table 1).

The NBN represents a mechanism for delivering biobanked material from a variety of cancer sites, sample types, and numbers required by industry.[20,21] For academics, the NBN represents a mechanism to provide the high volume of biobanked material required to establish robust genetic associations and to facilitate inclusion on pan-European and/or international studies.[20,21] The NBWP, currently under development with SuprTecBox Ltd, will allow researchers to explore biobanked material within the NBN and to customize investigations accordingly. An NBN could also reduce the use of international tissue procurement organizations by Irish companies, and thereby help to sustain the NBN and related infrastructures.

Large pharmaceutical companies are increasingly partnering with smaller entities to bolster their waning pipelines.[11] Forty percent of pipeline products are now sourced externally, as purchasing promising candidates is more cost-effective.[11,22] The dearth of novel pipeline therapeutics provides small indigenous Irish companies, higher education institutes, and spin outs, currently developing novel molecular entities, with an opportunity to broker high value intellectual property licensing and/or partnering models.[23–25] By engaging later in the R&D process, pharmaceutical companies can apply stringent criteria to minimize or reduce the risk of choosing a dead end pharmaceutical product. This should benefit Ireland's knowledge economy and promote Ireland as a viable R&D center.[11,23–25] Ultimately, to attract greater pharmaceutical R&D investment, Ireland must demonstrate that 1) cohesive biobanking, clinical trial, and research infrastructures are in situ, 2) excellent collaboration exists between academia and industry, 3) formal intellectual property and licensing agreements are in place between various higher education institutes and the pharmaceutical industry, and 4) that there is a national capacity to commercialize research.

Table 1 Comparison of industry and academia requirements

Industry	Academia
Broad spectrum research – companies typically investigating between four and 15 cancer sites simultaneously	Narrow research focus – the vast majority of researchers investigating one (47.7%) or two (25%) cancer sites
Highly variable sample types utilized	Highly specific sample types utilized
Short timelines	

Conclusion

The results of this pilot survey suggest that the benefits of an Irish NBN could be far-reaching and complement the numerous recommendations proffered by various government reports and strategy documents on the Irish pharmaceutical sector.[11,15,16,23–25] A properly resourced NBN–NBWP–CTOP infrastructure has the potential to streamline and transform how Irish researchers access biobanked material and associated

data. The need for a CTOP facility is emphasized by the drive to integrate biomarker discovery and validation into oncology clinical trials, via the provision of biobanked material. An NBN and supporting infrastructure has the capacity to enable Irish affiliates of global pharmaceutical companies to compete more effectively within their parent organizations, within Europe, and internationally, and to secure additional clinical trial opportunities and R&D investment.

Disclosure

The authors report no conflicts of interest in this work.

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