

Biobanking in a competitive environment: qualifiers and winners

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ABSTRACT

Why do researchers choose specific biobanks like UK Biobank, IBBL or Biobank Graz as valuable resource for their new research related to personalized medicine? Why are representatives of the Netherlands Cancer Institute, Estonian Genome Center and IARC so well represented in the setup of the European Mission on Cancer initiative? Biobanks must, similar like companies, earn their end-user's loyalty and respect, which in most cases results in fruitful partnerships. Terry Hill, former professor at the London Business School created the terms 'order winners' and 'order qualifiers' and what the difference is between them for a business environment. In many biobanks these two are not clearly defined or even mixed up, resulting in less optimal performance in sharing samples and data.

INTRODUCTION

Departments like a biobank within Universities and/or Academic Hospitals need a strategy that integrates the activities of the different units in order to achieve one common goal, which is set from the overall strategy; e.g. improving patient healthcare / lead in development and medical break throughs. Sustainability and business planning for biobanks is crucial but also within these plans the various initiatives and activities should serve the larger vision of the organization. The challenge here is that still biobanks are convinced that researchers have no alternative than to connect and partner up with them when looking for high-quality samples and associated data. In other words, researchers cannot go find a better alternative because there is none. The researchers themselves, however, are often convinced that there are many alternatives to biobanks, which is mainly due to the fact that sample collections hosted by biobanks lack visibility, findability, and accessibility or simply because researchers have a strong desire to have their own collections of specific material. According to Hill (2000), 'order winners and order qualifiers' refer to the process of how internal operational capabilities are converted to criteria that may lead to competitive advantage and market success. Hill advocated for a strong link between manufacturing and marketing, both departments need to agree and intend to serve the same markets in order to achieve an effective strategy. The marketing strategy also should be in line with the ability of the organization to deliver on that promise. Where academia and especially biobanks are not in the manufacturing arena there are similarities that are worth to have a closer look at. Hence, a market strategy based on market research can explain how a product or service can be competitive. As a result this also creates the basis for product development and how an organization should manufacture.

DEFINITIONS AND BACKGROUND

Hill's definition of a qualifier is *'those criteria that a company must meet for a customer to even consider it as a possible supplier'*. Providing or realizing these criteria doesn't guarantee that all orders will be won. If a biobank does not meet these minimum standards on order qualifiers, like for example patient consent, the researchers will ignore or reject the potential partnerships. The definition of an order winner is: *"those criteria that win the order"*, in other words, if you want to deliver order winners you need to surpass the competition. Market research is needed to understand the behavior of the customer and what their needs are. Here also market segmentation is needed; a segments consists of a group of organizations that share one or more characteristics, making them have similar needs (Robben 2012). Segmentation is more then just a numerical exercise: different segments simply require the allocation of different types and amounts of resources to address the segments' needs appropriately. Segmentation can be done on a variety of levels; there is a clear difference in population based versus disease based biobanks, both requiring different approaches, infrastructure and resources. Alternatively you can segment on type of samples and their use for future research; will this be for a variety of –omics studies, validation of biomarkers or starting material for a new vaccine or drug in a close cooperation with a pharmaceutical company?

QUALIFIERS AND WINNERS

There are a variety of different purposes and designs of biobanks, such as establishment for therapeutic or research purposes, and they can be operated by a public not-for-profit or private for-profit entity. In the human domain, biobanks are typically considered to be for research and are established either in the context of cohort studies (e.g., population-based cohorts funded by specific research programs) or in the context of health care (e.g. diagnosis and treatment of cancer). Although these different types and contexts of biobanks demand specific biobank designs and specifications there are two elements common to all biobanks and therefore could be defined as qualifier:

- 1) the resource (i.e. samples and data) requiring data provenance
- 2) the governance/management structure ensuring competent personnel, quality and data management, ethical and legal compliance as well as transparent and efficient access.

Several common qualifiers and winners will be matched with the biobank environment and some new ones introduced that are specific to the market

Figure 1. Wireless monitoring solutions, several options designed for stationary equipment as well as cold chain, plus new cloud-based solutions to support a connected lab and collect the required data for the specific processes



Reliable data provenance

Collecting the sample according to correct pre-analytical procedures sounds more obvious than in practice can be shown. In 2011 Lippi published that 60-70% of all problems occurring in laboratory diagnostics, most of them attributable to mishandling procedures during collecting, handling, preparing or storing of the samples. Less attention seems to be there of the various sources of data that create the real added value to the sample; radiological data, laboratory results, treatment information etc. In biobanking it is not always possible when working with high-quality pathological and clinical data to control all variables (especially in the preanalytical phase), but their documentation is important (Sargsyan 2018) If it is not clear who collected which data when, the collected specimens might loose a lot of value for potential research.

Quality

The ability to deliver high quality of samples was mentioned as one of the most important criteria in selecting a biobank by 57% of German researchers in a survey in 2019 (Klingler 2019) and therefore a good example of an order winner for (German) biobanks. Additionally the release of the ISO 20387 Biobank standard and the ongoing activities in external quality assurance programs (incl proficiency testing) further proofs the need for high quality samples and associated clinical data.

However, during many biobank events incl EBW 2019 in Lubeck it was also clear that quality in itself is a very wide concept and different parts can be either a qualifier or a winner and usually hard to define and classify. Garvin (1987) created a table that consists of eight different dimensions of quality where each of the dimensions should be analyzed when investigating important characteristics, with additional information from Sebastianelli (2002).

Table 1. The eight dimensions of quality – adapted (Sebastianelli 2002).

Dimension	Definition
Performance	The primary characteristic of a product or service
Features	The secondary characteristics of a product/service that supplements its basis functioning
Reliability	The product's or service probability of failure free performance over a specified period of time
Conformance	The degree of which a product's physical and performance characteristics meet design specifications
Durability	A measure of useful product life; the amount of use a customer gets from a product before it deteriorates or must be replaced
Serviceability	The ease, speed, courtesy and competence of repair
Aesthetics	How the product looks, feels, sounds; a matter of personal preferences
Perceived quality	Quality based on image, brand name, or advertising rather than product attributes and is subjectively assessed.

It is the biobank itself that has to define their specific qualifiers and winners, but help form outside is certainly something that could create a favorable position in the market and the way it is perceived by the end users.

Sample quality and integrity is an absolute winner for biobankers according to the German survey and here a variety of products and solutions is needed to build the biobank infrastructure in the first place. Just the procedure on who can store what within which time limits at what temperature still could be a failure with the wrong hardware.

The characteristics mentioned above and if they are a winner or qualifier, depend on the specific circumstances of the biobank and how mature the organization is. What is worthwhile mentioning that in the selection of equipment and process already selections are made about quality. Below an example of quality solutions, that support overall biobank high quality standards and potentially order winners (fig. 2)

Figure 2. Thermo Scientific™ Ultra Low TSX Freezers with hydrocarbon refrigeration system, designed for high reliability and long-term sample storage and Cryomed controlled rate freezers designed to control the rate at which samples are frozen and to usher samples through the latent heat of fusion given off by samples during the freezing process. Both supporting criteria to help the biobank achieve order winners on for example performance, reliability and durability.



Speed

The ability to deliver samples within a specific timeframe is crucial for the majority of researchers. Here there is a difference in understanding and also a good example on the importance of knowing your stakeholders and what their expectations are. Where a biobank that can deliver samples to a researcher in a timeframe between 8-12 weeks the overall experience is very good amongst biobankers, but CRO's or biotech companies need samples within weeks or even days as clearly presented by Mahon during this talk: Biobanking for precision oncology, the need for Scale and Speed at EBW2019 Lubeck. Both parties see the need for cooperation and are interested to explore opportunities, but time experience is completely different. Setting the right expectations, and being able to deliver within the agreed time frame will definitely be an order winner.

Service level

When a biobank is writing their business plan, they should consider what they want to focus on and that requires strategic decisions (Tracey, Wiersma 2001); The focus area can be: product leadership, operational excellence or customer intimacy. A certain service level from a biobank to a researcher that is based on exactly knowing the requirements of the end-user, try to find the best possible fit and build a long term relation based on trust creates automatically an order winner. A basic level of service is needed to be able to serve end-users, but going the extra mile that is also part of an overall strategy could make a difference and have a positive effect on the sustainability as well. Biobank Graz, IBBL or UK biobank clearly demonstrated a high service level, helping to build their brand and numerous researchers around the globe in search for specimens and data.

Data protection and privacy, GDPR

The best example of a qualifier is compliance with regulatory requirements, especially around data-protection and GDPR for European Biobanks. With the launch of the European General Data Protection Regulation in May 2018 there is simply no excuse not to have the right data protection in place of the patient/donor material. The applying researcher has to demonstrate the purpose of the research project, possible outcomes and risks, especially those that may affect sample donors. If the researchers plans to use retrospective samples the ethics body usually checks the original scope of the consent signed by the donor, before giving the final opinion. Only in certain situations when chances to reach the sample donor are relatively small the ethics body may extend the scope of consent by themselves or may wave the need for further specific consent. In other words, the researcher needs a biobank that covers this aspect of the specimens needed, in order to be able to start the planned research.

Discussion

Cost

In a business oriented environment price can be an order qualifier or winner, depending on the type of product and in which stage it is of the product life cycle. Biobanks that are part of the public domain can't 'sell' their samples and have in general two compensation models:

- Scientific acknowledgement in for example publications
- Cost recovery.

The second option, the price per sample, could technically be an order winner, but research shows (ADOPT BBMRI-ERIC, D 4.2 and D 4.3 ,2019) that biomedical researchers would find the prices too high when full cost recovery is in place, here are still a lot of discussions ongoing on the best way forward. It is clear however that long term sustainability of biobanks requires more funding than just covering marginal costs for sharing samples. In the future costs could be a qualifier or winner in an even more competitive market of biobanked samples.

CONCLUSIONS

Order winners and qualifiers are both time-specific and market-specific; they work in different combinations in different ways on different markets and with different end-users. Also a winner today, can be a qualifier in a few years from now; it is not always stable over time. In the early years of biobanking for example the number of samples would be order winners for the research community, where now the focus is more on the combination of sample material and associated clinical data, less on the total available number of specimens.

Going forward we can help you achieving the qualifying criteria for a biobank, but certainly enable biobanks to develop order winners as well. For more information on our solutions, please check this page here.

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