Design Considerations and Equipment of Biobanks

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Abstract

Talented researchers, scientists, data specialists and laboratory staff, for example, are without question a fundamental resource for a biobank. Supported by the right tools, they can work on the challenging scientific questions that need answers to better understand certain diseases or to be able to treat them with new drugs in the future. This chapter provides an overview of the main instruments, consumables and data management platforms for biobanks, including some considerations when designing a biobank from scratch.

Keywords

Design of biobank equipment · Key instruments · Consumables · Data management platforms · Automation systems · Maintenance · LIMS/BIMS

Equipment (and Some Design Considerations)

Talented researchers, scientists, data specialists and, for example, lab staff are without question a fundamental resource for a biobank. Supported by the right tools, they can work on the challenging scientific questions that need an answer in order to understand better specific diseases or how to treat them in the future with new drugs. What are the key instruments, consumables and data management platforms to consider? Here is an overview, including some considerations when designing a biobank from scratch.

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Building and Rooms

Multiple universities across the globe have allocated the biobank in the basement of one of their buildings; this seems a logical choice to keep the costs down and with limited space sometimes the only option available. Location selection should, however, not be underestimated, and an assessment of the risks involved for the specific site on, for example, lightning, earthquakes or flooding needs to be made. Facilities should also be prepared to address situations like power failure and emergency storage. Active planning and preparing for risk mitigation, redundancy and monitoring can help.

Consumables and Software

Careful planning and mapping the risks is also needed on the equipment side. Instruments, consumables and software all should be fit for purpose, and therefore it is crucial to have a clear vision on why you are collecting a specific set of samples and which potential research questions they could help to answer. This more strategic approach can also support in finding the right tactics as well as making the correct operational choices that need to be made when preparing for example the needed instruments and their detailed technical specifications.

Collection of Samples

A lot of work already starts outside the biobank site; samples need to be collected, forms to be filled and staff trained to support all the efforts. In this part of the process, there is not always the opportunity to select the samples, collection tubes or 1D barcode characteristics; however, it is crucial to be aware of what is used for which part of the collection process and what to expect once it arrives at the reception desk of the facility. Buy in from other parts of the organization that are crucial for a biobank to be successful might be more important than dictating a specific new tool or product.

Arrival of Samples at Biobank Site

Upon arrival of samples at the biobank site, the correct registration of the samples takes place, and already there some critical time steps will start, and potentially specific actions need to take place. In many cases, the so-called mother sample will receive a new unique ID, also to be compliant with internal anonymization or pseudonymization procedures. Warning flags should be automatically raised when inconstancies occur like missing data, incorrect data, damaged collection tubes or incorrect minimum volume of the material. Depending on internal procedures, this

might also be the moment to record if the donor or patient wants to be informed in case of incidental findings.

Automation and Maintenance

Numerous biobanks nowadays are using full or almost full process automation and are taking benefit of the modern well-developed instruments for biospecimen management. Data management tools are considered to streamline instrument and automated system integration. Formerly incongruent biobanking infrastructure components can now be combined to open the possibility for data to be electronically distributed among them, excluding manual error-prone procedures and rising efficiency and data consistency. Instruments itself contain predictive maintenance programs and allow remote diagnostics and performance management to lower the total cost of ownership. Implementing ISO 17025 and/or ISO 20387 (the new biobank standard) can support and capture in these instruments' requirements. According to these ISO standards, equipment should be provided by selected suppliers that are regularly audited. Maintenance should be scheduled, and only properly trained staff is allowed to do specific maintenance, calibration or servicing. Building a track record of when which instrument is checked by who helps to be in control, be ready for audits and increase the quality of operations in general.

Aliquoting and Collection Tubes

Next steps in the process of a unique biobank sample strongly depend on the setup of the biobank and which goals need to be addressed. Assuming several copies will be made from the original sample aliquoting is needed. Here another paramount decision needs to be made first: in which sample storage tube will the aliquot be transferred to? Once the number and volume of the aliquots is decided, a sample storage 2D collection tube can be selected, which is also an important factor in the path towards standardization. The permanent 2D barcode creates a solid, proven way of tracking the sample during its lifetime in the biobank. In combination with barcode readers, sample data can be integrated into existing databases or tracking systems. The tubes will be ready to be utilized for storage in nearly any laboratory condition, from room temperature to the vapour phase of liquid nitrogen.

Choice of Collection Tube

Where there are literally several dozens of different tubes available, biobanks still have too often the tendency to request for a custom-made special tube that would fit their processes better. This is not only challenging for the manufacturer from a quality, stock and logistics perspective but also interoperability becomes an issue. Biobanks providing samples in formats that cannot be handled outside the

organization create an additional hurdle for them to be used. Several automated storage systems are modified as well to fit the custom tube, involving additional investment without clear evidence of additional value to research. Supporting instruments like Capper/Decapper can support for optimization of benchtop processing of screw top storage tubes, maintaining crucial sample integrity.

Liquid Handling

Assuming a significant throughput of samples is required, automated liquid handling comes into place. The majority of the solutions provided is able to interface with the Laboratory Information Management System (LIMS) to receive worksheets on which sample to take, how much volume from and in which rack with tubes this should go to. In combination with the 2D barcode scanner and the liquid handler software, the exact location and information of each sample is available, again supporting a full audit trail. From a redundancy point of view, it might be good to invest simultaneously in a backup or second liquid handler, so in case something is not performing as planned, not the whole process stops and the quality of received samples might be in danger.

Cold Sample Storage

Depending on the sample type, the purpose of storing and the period of storage, the temperature conditions can be determined [1]. All matrices have their own optimal storage conditions, and handling at temperatures outside these ranges can cause significant sample stress as a result of cellular dehydration or ice formation. Similar as with other steps in the process, careful planning is crucial to maintain sample integrity and to prevent samples from becoming too warm or too freeze due to direct contact with dry-ice. Here the best option to keep a sample between +1 °C and +10 °C is to use a water/ice slurry. The sample type should also determine the rate at which a sample is cooled for storage and eventual thawing. When selecting the right cold storage solutions, keep in mind the fit for purpose; domestic, residential or white boxes do not meet the rigid temperature control, stability and uniformity requirements.

Backup Storage

Backup storage units that already have the right temperature, have ample reserve of LN_2, dry ice and have generator fuel onsite are critical. Obvious measures, but surprises can still occur and thawing of frozen samples and freezing of refrigerated samples should be prevented. Active and regular monitoring beyond only temperature, but also on relative humidity and/or CO_2 concentration, supports to identify issues at an early stage, or even prevent them from happening altogether. Secure data

logging and automatic audit trials support regulatory compliance as mentioned earlier.

Automated Cold Storage

In recent years, the interest in automated −80 °C storage has increased and implemented in a number of biobanks in Europe, Middle East, Asia and North America. Reasons for making the investment has been the capacity, the availability of space and the usage of energy on one hand, on the other hand to fulfil projected requests for samples in a high-quality environment. Where this can be true for some biobanks, the majority does not need these capital-intensive investments to run the biobank in line with the highest-quality standards. If there is funding to make larger investments, it might be worth to consider managing the data as best and secure as possible to be ready for future demand.

Laboratory Information Management Systems (LIMS)

The actual registration and many other process steps require a data management system. Changes in technology and connectivity have influenced data management in the last decade significantly. LIMS solutions are already available for decades for various types of industries with hundreds of thousands of users globally every day. Due to the maturity of the solutions, the experience and knowledge of the providers and active user communities, updates and upgrades are available on a regular basis and strong organizations can help out with maintenance and support. Downside is the relative high investment and running costs in comparison to the functionality that is used.

Biobank Information Management Systems (BIMS)

In response, some software developing companies created a BIMS. A BIMS is a dedicated solution that specifically focuses on the challenges within a biobank, not only sample management on who logged which sample at which moment and managing critical times between taking and freezing but also on the consent status of the samples/donor to make sure it is only used in the right studies and it is flagged for what should be done in case of incidental findings. Going forward, there are still discussions on how to do this, and therefore flexibility can be an option. For both LIMS and BIMS, it should be taken into account that it requires dedicated internal resources for first-line support and can also support change requests. Acknowledging the fact that a sample does not have a lot of value for research if it misses the associated data, the investments needed should be budgeted to prevent incorrect data or unclear data provenance.

Homegrown LIMS/BIMS

Inside academic institutions, it is still popular to apply for specific grants to support a small team of computational scientists/software developers and programmers to develop a homegrown LIMS/BIMS. Great advantage is that it can be made exactly to the wishes of the end-user and no perpetual investments in license and support fees are needed. Where this may seem to be an effective option from a cost perspective point of view, but more and more biobanks do not see this as a sustainable way forward.

This kind of tools will be hard to create with a homegrown solution. In LMICs, it is best to go for a proven online system that can do the job. This is the way that the vendor can help out online, etc. If people need to be onsite all the time, you lose too much money on travel and manpower. Keep an eye on security.

Just like biobanking is a discipline on its own requiring specific expertise, so is data management. The often-made remark that data is as important as the sample makes this clear. Invest properly in a data management solution, supported by the right staff. If there is no real IT support available within the biobanking itself, it will be hard to manage.

Reference

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