Major project management pitfalls of clinical projects and how to avoid them

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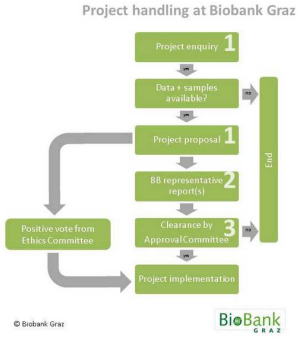
Background

Modern biobanks are no longer seen as storage facilities only, but rather as central hubs for biomedical research. In addition to biospecimen collection, processing and archiving, they are also involved in management of clinical projects. Project management in a biobank includes diverse tasks: donor selection, clinical data acquisition or cost calculation for biobank services.

Methods

Biobank Graz successfully processes inquiries from academic and industrial research for more than 10 years and provides samples to researchers all over the world. The project database of Biobank Graz comprises all inquiries since its foundation until today. Systematic evaluation of these requests allowed us to identify the major pitfalls during project planning and implementation, as well as the most frequent causes for project delays and cancellations.



Results

The lessons learned during 10 years of experience in management of clinical projects were collected, summarized and divided into different categories. By this means, we were able to identify the 7 major project management pitfalls of clinical projects. These pitfalls include different scenarios from simple communication problems and planning mistakes (e.g. appropriate control cohort) to more complex bottle necks (e.g. availability of clinical data). We provide tips and helpful hints for the daily work of project managers in biobanks in order to avoid common pitfalls.

Major Pitfall	Description	Avoidance Strategy
Insufficient information on the required samples	Before starting a new project, details on the required samples need to be clarified. The required information includes the number of samples, pathological / clinical diagnosis, clinical data needed, specific inclusion and exclusion criteria, etc.	Asking the right questions may be helpful: e.g. “Do you need a control group as well?” or “Are you sure that these samples are suitable for your analytical method?” => Write a statement of requirements!
Incorrect Ethics Procedure	Next to a thoughtful study protocol, a well-considered application for ethical approval is a crucial success factor.	Determine the study design (e.g. retrospective or prospective study). In case of a prospective study, prepare the informed consents you will use (e.g. broad IC or specific IC). Also, think about data security (coding of samples and data: pseudonymization / anonymization).
Retrieval of clinical data	At the beginning of a new project, attention is mainly focused on the most obvious requirements (e.g. number of available samples). Nevertheless, keep in mind that the bottle-neck of most projects is the retrieval of clinical data. Therefore, it is crucial to define right at the beginning which data are obligatory and which data are nice to have.	Prepare a structured template sheet for data retrieval and talk to the responsible MD or study nurse to clarify which data are available!
Unclear project partners	Many projects start with a long list of partners that seem to be involved in the study. It may be necessary to sort out at the beginning who is really involved in / responsible for / willing to work on the project.	A project kickoff meeting can help to get everyone on the team behind the project and to define responsibilities! E.g. Who is in charge of the pathological assessment of samples / the retrieval of clinical data / sample analysis, etc.?
Underestimating time and budget	Project management statistics and daily experiences tell us that most projects run over time. Therefore, it is important to carefully calculate how much time and budget you would need for a specific project.	A little bit of buffer time and extra budget is never a bad idea!
Not being flexible	No matter how precisely you have planned a project in advance, something unpredictable may always happen, e.g. there is an unwanted heterogeneity in you cohort or some data are not available for all patients (retrospective data collection).	The only way to circumvent this problem would be to retrieve all clinical data and to prepare all samples in advance (meaning before order confirmation). Of course, this is impossible if you have more than 300 requests p.a. Hence, some flexibility in both directions (client as well as sample provider) may be required.
Biological materials are no customizable products	Finally, it is important to explain to clients that it is impossible to “order” samples from a biobank as you order custom-built furniture from a carpenter.	Biological materials are derived from living organisms and therefore no sample is exactly like any other.

Conclusion

Biological materials are retrospectively not customizable, thus not everything is predictable in biobank project management. However, awareness of the 7 major project management pitfalls contributes to effective and successful project development and management in the highly interdisciplinary environment of biobanks.

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