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Introduction

Large scale cancer projects such as the International Cancer Genome Consortium (www.icgc.org) demonstrate the power of comprehensive genomic characterisation for understanding cancer biology and impacting patient care. This has stimulated a growing demand for appropriately qualified tumor specimens world-wide. However, tissue acquisition and resource development have proven to be the rate limiting factor.

We have identified at least three important bottlenecks:

- Ethical Issues
- Sample Collection Strategies
- Adequate Clinical Annotation

We present the experiences of the Australian Pancreatic Cancer Genome initiative where we have formulated an action plan for the construction of a genomics ready bio-resource.

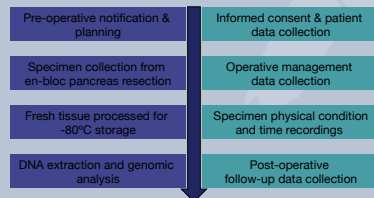


Figure 1: Prospective tissue acquisition and patient clinical data collection – generation of well annotated high quality analytes.

Ethics

The nature of ICGC data raises novel human subjects protection issues.

Core Bioethical considerations are:

1. Initiating flexible informed consent to allow re-contacting of patients for follow up or to obtain additional samples
2. Allow for broad sharing of de-identified biospecimens and data amongst ICGC investigators
3. That data will be accessible electronically to the research community under the auspices of the ICGC

The following strategies assisted the expedition of the approval or amendment process:

- Describe modern genomic studies in a level of detail applicable to ethics committees on application
- Use a nominated ethics officer at the local institution as the point of contact and fully brief them on history of the ICGC and related projects
- Attend HREC review meetings and answer any concerns up-front and openly

Sample Collection

The collection, processing and analysing of high-quality biospecimens is a critical initial step in this project. Minimum standards for sample size and composition, preservation techniques and sample data collection must be defined up-front to ensure that samples are fit for scientific purpose.

Targets are unable to be met from retrospective collections alone and prospective collections were initiated at networks across Australia. Figure 2 outlines tissue collection strategies.

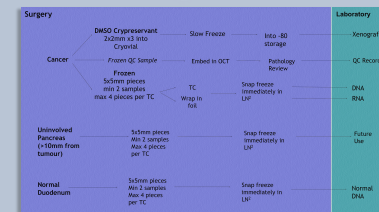


Figure 2: Tissue collection strategy outline

High quality collections can be ensured by:

- Developing Standard Operating Procedures for all steps
- Use best practice standards with local innovation so processes seem practical to participating sites
- Sample harvesting must overseen by a member of the research team to ensure adequate sample collection
- Document OT procedures that are critical variables that may affect quality of analytes
- Involve all stakeholders, get feedback about barriers and educate at every step

Clinical Annotation

Development of common data elements and a minimum data set will facilitate accurate data acquisition and sharing, and ensure clinical correlation with genomic data.

- Develop data sets with clinical input and build relationships with treatment teams
- Standardize documentation
- Use a compatible data storage format (CanSto Pancreas)
- Strategize collections to obtain data at crucial points along the treatment journey

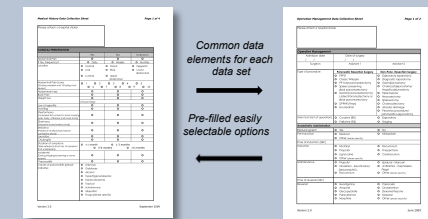


Figure 3: Standardized documentation of data points via user friendly collection sheets

Conclusion

Understanding of the underlying genetic diversity in cancer is likely to increase the success of new cancer modalities in the future. It is dependant on a high-quality biobank with highly standardized processes developed at the projects initiation, with complete documentation of all critical factors.

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www.pancreaticcancer.net.au

