Gynecologic Cancer InterGroup
Translational Research Brainstorming
October 2016 Lisbon

Roadblocks to Completing Translational Goals in Gynaecological Cancer Research

Ensuring Access for Future Research to Clinically Annotated Tissue

Ros Glasspool SGCTG

Potential Roadblocks

- Financial
- Practical
- Legal
- Ethical
- Professional

Financial

- Costs of taking samples
- Costs of transporting samples/blocks to research centre(s) and back to original hospital
- Costs of storing samples and/or data
- Governance

Practical

- Pathology review processes
- Tissue handling
- Ongoing sample quality
- What, where and how much is left?
- Return of samples

Legal

- Transfer of samples across borders
- Ownership of IP
- Destruction of samples
- Data protection laws

Ethical

- Consent to future research
- Consent to transfer of samples to other institutions and countries
- Ability to withdraw consent
- Data protection and privacy
- Recontacting with new genetic information
- Expertise of national or institutional review boards/ethics committees

Consent

- **Specific consent**
  - limited to data generated from a particular research protocol, applied for a specific disease type.
- **Specific and "related conditions" consent**
  - adds the possibility for the consent for use of research data to be extended to other, related disease domains.
- **Tiered consent**
  - series of options is provided and the research participant is able to indicate consent for one, some or all of the options indicated.
- **Dynamic consent**
  - a continuous consent process, with the opportunity for the participant to indicate their consent (or lack of consent) for their data to be used in an evolving series of research studies that develops over time from the original research protocol.
- **Broad consent**
  - consent for future unspecified research studies, whose ethical principles are ensured through oversight from an independent research-ethics committee.
- **Open consent**
  - For an open consent model, all future biomedical research is indicated, with resulting research data becoming accessible to other researchers.

Adapted from L Siu et al Nature Medicine 22, 464-471 (2016) GA4GH

Gynecologic Cancer InterGroup
Translational Research Brainstorming
October 2016 Lisbon

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

Professional

- Collaboration and Co-operation
- Competition

"It is amazing how much we can accomplish when it doesn't matter who gets the credit."

Gynecologic Cancer InterGroup
Translational Research Brainstorming
October 2016 Lisbon

- Loss of control
  - Desire that precious samples be used in an optimal way
- Concerns that the results, scientific rewards and recognition derived from sample/data sharing, may not be equitably shared with those that contributed them
- Incentives for data sharing may need to go beyond acknowledgement and authorship
  - Flow of information two ways
  - Training fellowships
  - Bioresource research impact factor*

*Bravo et al. BMC Medicine (2015) 13:33

What Can We Learn from Others?

- Very successful initiatives in other tumour types eg BIG
  - MINDACT: > 6 000 patients 52 000 samples 47 million Euros
  - AURORA metastatic breast cancer study: 1000 women and men from over 80 hospitals across Europe collecting biopsies from primary and metastatic tumours, plasma and blood samples.
  - Innovative bioinformatics platform designed to allow sharing with other initiatives in the US and Canada.
  - Biorepository
  - Video in multiple languages describing sample handling
  - Steering committee and Molecular advisory board, patient advocates, scientists, pathologists, oncologists, geneticists, bioinformaticians
  - Associated clinical trials

Global Alliance for Genomics and Health GA4GH

Aims to create a common framework of harmonized approaches to enable the responsible, voluntary, and secure sharing of genomic and clinical data.

- Clinical Working Group aims to enable compatible, readily accessible, and scalable approaches for sharing clinical data and linking genomic data.
- Data Working Group working on data representation, storage, and analysis of genomic data and to develop approaches that facilitate interoperability.
- Regulatory and Ethics Working Group focuses on ethics and the legal and social implications, including harmonizing policies and standards, and developing forward-looking consent, privacy procedures, and best-practices in data governance and transparency.
- The Security Working Group work on the technology aspects of data security, user access control, and audit functions, working to develop or adopt standards for data security, privacy protection, and user/owner access control

GA4GH: Framework for Responsible Sharing of Genomic and Health-Related Data

- a fundamental human-rights perspective that emphasizes both the rights of all citizens to benefit from the advances of science and the rights of scientists to be recognized for their work.
- 1948, article 27 of the *Universal Declaration of Human Rights* proclaimed that 'Everyone has the right to share in scientific advancements and its benefits … and the right to the protection of the moral and material interests resulting from any scientific … production of which he is the author'
- Complements conventional bioethics principles,
- embeds responsible clinico-genomic data sharing within a recognized and endorsed international legal framework.

Bartha M. Knoppers, Jennifer R. HarrisIsabelle Budin-LjøsneEdward S. Dove
Human Genetics July 2014, Volume 133, Issue 7, pp 895–903

Gynecologic Cancer InterGroup
Translational Research Brainstorming
October 2016 Lisbon

Gynecologic Cancer InterGroup
Translational Research Brainstorming
October 2016 Lisbon

Gynecologic Cancer InterGroup
Translational Research Brainstorming
October 2016 Lisbon