Challenges for Industry Working with Academic Biobanks: Survey Supported by the ISBER Pharma Working Group

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Background:
For industry, accessing biospecimens from Academic Biobanks (ABs) often involves long and complex discussions. To better understand their practices, expectations and challenges of industry, a survey was done. The aim of this study is to inform ABs of the existing needs, requirements, and challenges of industry with goal to enhance access and interactions between academic biobanks and industry.

Methods:
A questionnaire was sent to 160 different pharma, biotech and diagnostic companies (SurveyMonkey). Thirty questions or categories: specifics, challenges, requirements. So far it was completed by 36 companies, including 12 big pharma.

Results:
• Industry Practices:
  - Final use of biospecimen can be for discovery and research, for clinical program advancement, assay development, regulated environment.
  - About one third are ordering between 11 and 50 samples, one quarter between 51 and 100, and one out of eight biospecimen collections includes more than 200 biospecimens.
  - After cancer, most of the biospecimen needs are for infectious diseases and CNS diseases. FFPE tissues (for cancers) and serum/plasma are most frequently requested. Samples from healthy donors are also highly sought.
  - About two third of the companies have preferred sources for their samples. Besides their in-house biobank, < 40% of biospecimens are sourced from ABs vs. 50% from commercial vendors. Though commercial or broker sourcing thought easier and faster, some main concerns were noted: i) location of collection not disclosed; ii) no opportunity to interact with academic medical team; iii) clinical information often limited.
  - 76% respondents have difficulties locating / identifying sources or Abs for specific biospecimens required for their R&D (not only from diseased patients but also from healthy subjects or non-diseased comparators).
  - 89% consider AB collections underutilized and unable to respond to R&D needs.
  - High level of trust in quality of biospecimens or associated patient data from ABs.

• Main concerns:
  - Time spent for internal administrative process and establishing a contract.
    o Often require use of AB MTA/MSA template (English)
  - Requirements from some Universities for access to biospecimens:
    o Intellectual Property rights
    o Research collaboration
    o Use of Academic laboratory platform for all or select analyses
  - Requests for acknowledgment or co-authorship (when appropriate) in scientific publications were thought justified.

• Gap in common understanding:
  - Requirements from regulatory authorities for approval process
  - Challenges of patent law and IP protection.
  - A transparent cost model would be appropriate for end-users, academic vs. industry

Conclusion:
Industry regards ABs as ideal partners for:
• Access to quality biospecimens and clinical annotations
• Critical and valuable expertise in common diseases of interest

A few ABs are responsive to industry, open to collaboration without restrictions, and have streamlined access but they remain a minority. There is still a lot of education needed on both sides to facilitate successful collaborations. Further discussions between parties would help ABs to valorize and sustain their own biospecimen collections. Patients would benefit from innovations more rapidly.

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