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Challenges of international human biospecimen biobanking for biomedical research in the era of personalized medicine

Translational medical research, including the development of new drugs and novel biomarkers, companion diagnostics and, overall, personalized approach in medicine. Biomedical research requires a continuous supply of legally and ethically acquired high-quality human biospecimens and associated clinical and molecular data. Important topics of human tissues research include (a) Building an effective value chain framework for biobanking. This is a complicated process and this is why the pharma industry prefers outsourcing the procurement of HBS (human biospecimens). (b) Global regulatory compliance and ethical/legal issues on global human tissue procurement for research purposes, including international disparities in regulations on the use of human materials for biomedical research. (c) Creating fit-for-purpose collection protocols and standardized Informed Consent Forms allowing a wide range of applications for collected HBS (NGS, single cells analysis, etc.), including future technological advances. (d) Creating and managing an effective global clinical network. (e) Clinical data collection and management, HIPAA Privacy Rules for research specimens, variabilities in the international regulations. (f) Cost of biobanking, available resources and strategies for creating a self-sustaining biorepository. (g) Public resources for data and protocols: TCGA (The Cancer Genome Atlas); CPTAC (Clinical Proteomic Tumor Analysis Consortium): ISBER, CAP, NCI.

Biography

Olga Potapova is a life sciences executive with extensive scientific and project management expertise in translational oncology, diagnostics and laboratory medicine. She worked on the development of targeted therapies (SUTENT) and human prenatal diagnostic tests (Cystic Fibrosis); coordinated major international collaboration projects with an emphasis on RTK signal transduction research, human biospecimen procurement, preclinical and early clinical development. Currently, she leads Cureline group, a global CRO with emphasis on HBS biobanking, laboratory services and glyuco biomarkers. She has received multiple AACR/AFLAC awards, NIH and NATO fellowships and has published multiple scientific papers in peer-reviewed journals. Since 2010, she has been a Principal Investigator for The Cancer Genome Atlas (TCGA) program and since 2015 for the Clinical Proteomic Tumor Analysis Consortium (CPTAC) program (both NCI, NIH). She has advanced degrees in Physics and in Molecular Genetics/Biochemistry.

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