BIOREPOSITORY RISK MITIGATION PLAN: THE VALUE OF SPECIMEN STORAGE FOR CLINICAL RESEARCH

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YOU DON'T KNOW WHAT YOU'VE GOT UNTIL IT'S GONE

The number of natural disasters globally has quadrupled to around 400 a year since 1970.[1] According to Aon's Weather, Climate, and Catastrophe Insight: 2019 Annual Report, the economic losses hit nearly $3 trillion - up from 1.8 trillion recorded between 2000 and 2009.[2] The United States alone has experienced more billion-dollar natural disasters in the last few years than ever before with $232 billion recorded in losses.[3,4]

The biomedical research community has also felt the impact of natural disasters over the last decade with multiple accounts of loss and destruction documented. After Hurricane Sandy, the Smilow Research Center Medical Science Building at NYU Langone experienced extensive damage noting that everything in its basement was destroyed. David Gresham of NYU Langone described the event as an "astronomical" loss of time and effort.[5]

For those banking biospecimens, the above stories are foreboding. In a process-oriented industry that breathes deeply from a standard set of regulations, it is easy to see the importance of each storage unit in the repository and the value of biorepository risk mitigation planning.

THE VALUE OF A SPECIMEN

Samples from subjects provide critical data to drive research, clinical programs, and ultimately regulatory submission and successful marketing. These samples are also used for method development for proof of concept and are relied upon for assessing responses to therapeutics, and therefore considered invaluable, but not incalculable.

The cost, in part, is attributed to efforts during early research as well as what is needed to manage study efforts through the broader clinical trial continuum. The total cost of developing a drug candidate from early research through to successful filing can be $800M to over $1B depending on the drug entity and pharmaceutical company.[6] Further, depending on the therapeutic area, the average cost of Phase 2 clinical trials can range from $7 million to $19.6 million. In comparison, the average cost of Phase 3 clinical trials ranges from $11.5 million to $52.9 million.[7] In addition to cost, time and patient data are critical as Phase 2 clinical trials generally span one to two years with hundreds of subjects, and Phase 3 clinical trials are longer, but with up to ten times the number of subjects.[8] With this information, one could estimate the economic value of a sample to help drive a risk mitigation plan for their specimens.

Additionally, other attributes of sample storage (e.g., restriction on legal use, intellectual property, etc.) should be considered with the derivation of any cost-model. But from a pragmatic point of view, it is these qualitative attributes that can genuinely influence the perception of the sample value.

A COMPREHENSIVE RISK MITIGATION PLAN WITH MEDPACE BIOREPOSITORY

Medpace has created and exercised disaster and risk mitigation plans with mock-up scenarios to anticipate measures and avoid ruin. We know firsthand about our levels of preparedness and continually make improvements to our plans. As a regulated facility, Medpace follows compliance constraints to ensure proper processing with written policies demonstrating control and competence for Sponsors.

Key components in a comprehensive biorepository risk mitigation plan:

- **Assessing and Developing a Strategy:** Conduct a threat assessment analysis to determine needs and risks
  - **Medpace**
    - Our experts will work with you to develop the best plan to mitigate your risks and have plans and agreements in place ahead of time. Working with an experienced partner and building a relationship strengthens risk mitigation plans.
    - We will evaluate your in-house situation and develop a gap assessment that identifies risks as well as recommending a mitigation plan.
    - Elements of the plan might include moving storage units to our site or improving your business continuity by duplicating and splitting your inventory.
- **Contingencies:** The Biorepository facility should utilize multiple and redundant back-up processes
  - **Medpace**
    - Biorepository with a dedicated generator, and a secondary generator failover
    - Cold rooms with redundant compressors and LN2 back up
    - Cryogenic room with a continuous feed from on-site liquid nitrogen bulk supply
- **Control and Security:** There should be levels of security and an environmental system for 24/7 monitoring specimens
  - **Medpace**
    - Rees Centron Presidio is the environmental monitoring system that manages controlled temperature storage units and areas
    - Restricted card access and actively monitored cameras located in critical areas of the Biorepository.
    - After-hour security patrol of the Biorepository in designated areas
- **Specimen and Data Accessibility**
  - **Medpace**
    - Critical inventory records and data are backed up and stored with us with an offsite redundancy server
    - Clinical study data are available through our web-based portal
    - Specimens can be retrieved at your request and within an agreed-upon turnaround time (TAT). Access to quality specimens must not be the rate limiter with clinical research.
- **Partner:** You want to select a specimen storage facility not just on size alone, but the fact that they have practical experience managing specimens for critical requests.

COMPREHENSIVE BIOSPECIMEN MANAGEMENT SOLUTIONS

Medpace recognizes that translational medicine is driving an evolution in sample management and that samples are highly strategic assets. Biorepositories are a critical component of any clinical study, given the need for high-quality specimen management. As the costs of clinical research and the risks of natural disasters continue to rise, establishing a biorepository risk mitigation plan as part of a long-term strategy is necessary for research.[9] Therefore, we focus on comprehensive sample management solutions for Sponsors to ensure end-to-end full-service capabilities.

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FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.