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FAST BREAK

PERSONALIZED MEDICINE AND CLINICAL TRIALS IN 2023

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Agenda

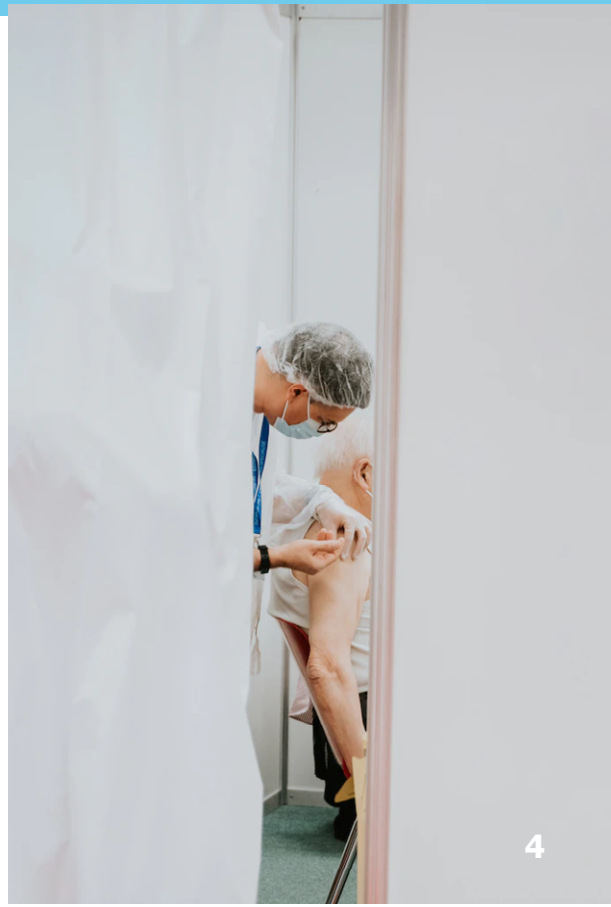
- Decentralized Clinical Trials and Considerations;
- Personalized Medicine “Manufacturing” Considerations

Decentralized Clinical Trials Potential

- Patient-centric approach to research that may address issues with time, cost and low participation rates
- Ability to conduct study-related activities in or near a patient's home
- Documented increase in value – reduced clinical phase cycle times, screen failure rates, and substantial protocol amendments
- DCTs can result in better compliance with trial protocol and governance adherence, improved patient recruitment and retention, and improved patient experience and overall engagement

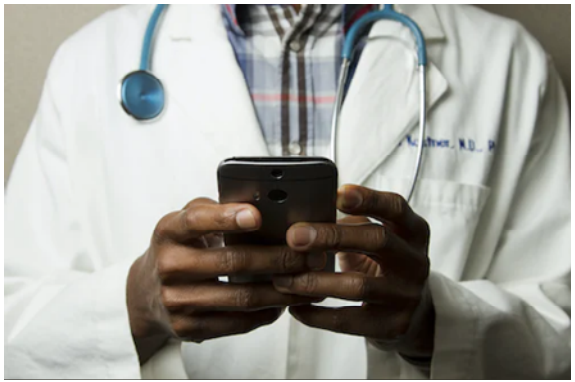
Decentralized Clinical Trials Potential

- Potential to improve racial and ethnic diversity, age groups, and accommodations for disabilities in clinical trials by offering services in patients' neighborhoods
  - Potential significant advantage given the current focus on clinical trial diversity and representation
- Encourages use of electronic informed consent and new strategies for collecting electronic patient-reported outcomes
- Remote monitoring through connected devices



Key Considerations for Implementation of DCTs

- Assess risks
  - Trial design and implementation is likely to be adaptive based on how the protocol and trial functions in the real world
  - Create contingencies to minimize impact of risks (e.g., digital tool malfunctions)
- Consider the site's abilities and logistics required as part of the protocol
  - Travel time/commitment for home visits (pros/cons of geofencing)
  - Insurance coverage/liability for procedures performed at a subject's home
- Consider trial participants' abilities and preferences
  - Ability to use electronic tools
  - Comfort with limited/no face-to-face interactions
  - Ability to self-administer therapeutic agent
- Establish clear lines of communication
- Ensure internal procedures are adapted for the new way of conducting trials (e.g., investigational drug accountability, adverse event collection and reporting, data recording, etc.)
- Consider licensing needs



Key Considerations for Implementation of DCTs

- Role of sponsor vs principal investigator
  - In conjunction with the sponsor, carefully define the role of each party in each trial setting setting (e.g., at the clinical site, at the trial participant's home, etc.)
    - E.g., selection of vendors
  - Ensure alignment on oversight/ supervision responsibilities (e.g., home health nurses, non-study HCPs dispensing/administering investigational product, etc.)
  - ACRP: Consider the perspective of personnel working at clinical research sites and involve all trial stakeholders in decision-making to ensure the effective implementation of decentralized clinical trials
  - AEs: Understand AE reporting to avoid duplicate reports when AEs can be reported through multiple channels (digital tool, external healthcare professional, or trial participant)

Personalized/Individualized Medicine Potential and Decentralized Manufacturing

- One of the biggest developments in the last 10 years has been the evolution of personalized medicine
  - Off the shelf medicines based on biomarkers→cell/gene therapies specifically designed for an individual patient
- May require involvement of the HCI in productions steps
  - Collection/preservation of "raw materials" to point of care manufacturing
  - Use of portable manufacturing units
- Provides advantage of having the drug at the patient's location for fast delivery
- Raises a number of questions as it challenges the traditional manufacturing paradigm

Distributed/Point of Care Manufacturing Questions- FDA is thinking about these issues

- October 2022 FDA Discussion Paper on Distributed and Point of Care Manufacturing raised a number of questions regarding regulation
- Distributed Manufacturing-"A decentralized manufacturing strategy consisting of a manufacturing platform comprising manufacturing units deployed to multiple locations." E.g.:
  - Units located within manufacturing facilities operating within the host's pharmaceutical quality system (PQS).
  - Units manufactured and installed to the same specifications at multiple manufacturing facilities, networked and operated by a central remote PQS.
  - Units as independent manufacturing facilities, each with its own PQS.
- Point of Care Manufacturing-" A subset of DM that uses manufacturing units distributed to host sites in proximity to patient care (e.g., health care facilities)"

Distributed/Point of Care Manufacturing Questions-FDA Key Considerations

- When does manufacturing begin?
- How do we ensure harmonization with the sponsor's product approval?
- What licensing is required?
- Will the facility be inspected and is it inspection ready?
- What contractual arrangements are required?
- How is risk/liability distributed?
- How is quality assured?
- How are people trained?
- Are facilities adequate?
- How are issues identified and remediated?

Thanks and Be Well!

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Jacqueline Berman advises companies throughout the US Food and Drug Administration (FDA)–regulated product supply chain on regulatory and compliance requirements. Jacqueline helps clients navigate complex issues associated with development, approval, and commercialization of prescription and non-prescription pharmaceuticals and biologics, including vaccines, and cell and gene therapies. Jacqueline further counsels clients on legal requirements under laws enforced by the US Consumer Product Safety Commission, Federal Trade Commission, US Drug Enforcement Agency, and state licensing agencies for consumer products, controlled substances, pharmaceuticals, and medical devices.

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

Thanks and Be Well!

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Alexandre Gapihan's practice is primarily focused on matters relating to the Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), and the pharmaceutical industry, including the approval, regulation, promotion, and sale of drugs, medical devices, and dietary supplements. Alexandre excels in assisting clients in navigating the complex legal and regulatory frameworks that impact their business.

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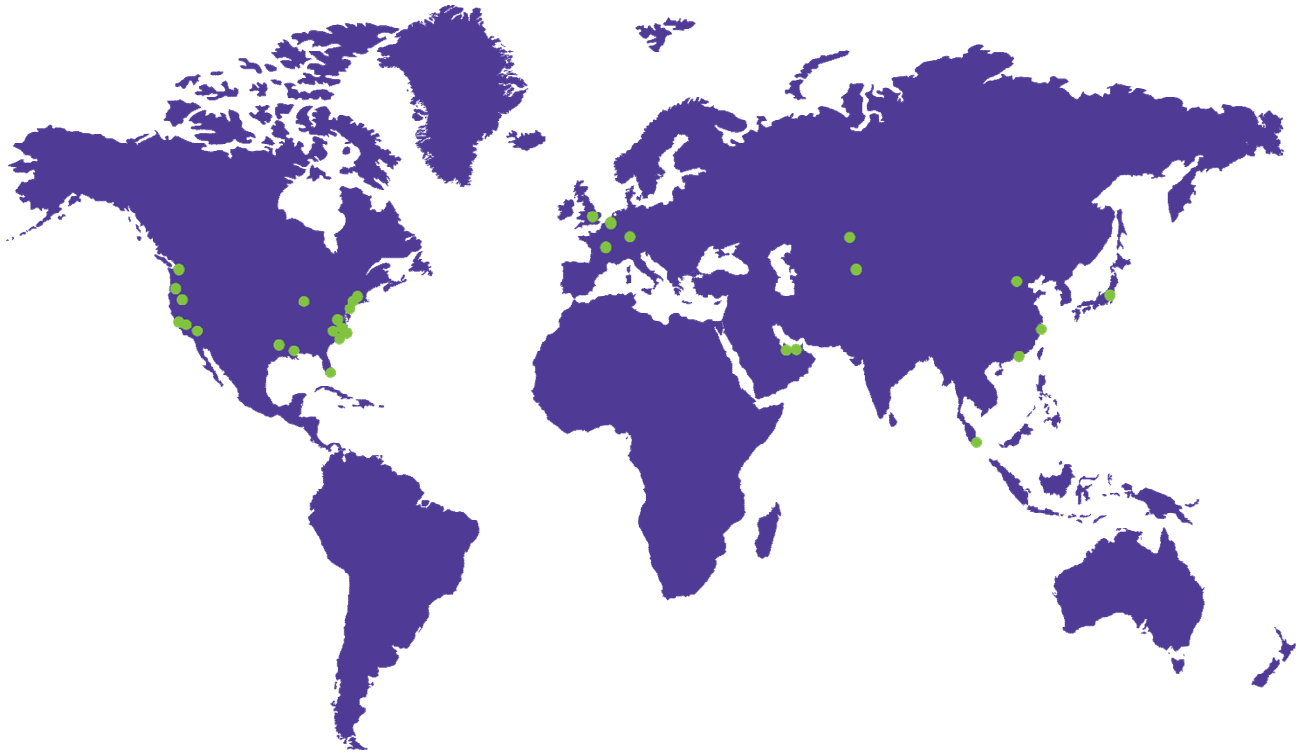

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