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Dr Leen Kawas Discusses 5 Trends Helping to Transform Clinical Trials in 2024

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A well-managed clinical trial can help determine a drug candidate's safety and efficacy. Defining the clinical trial parameters requires consideration of multiple factors, and many strict requirements must be satisfied. Recruiting enough eligible participants to complete the evaluation is an ongoing challenge. Many otherwise eligible individuals are far from testing locations and/or lack the funds to relocate for the trial's duration.

With these hurdles as a backdrop, diverse stakeholders continue their efforts to revamp clinical trial protocols and address perceived deficiencies. Leen Kawas, Ph. D., is Propel Bio Partners' Managing General Partner . She previously served as Athira's Chief Executive Officer (or CEO). In this capacity, Dr Kawas managed several drug development cycles and oversaw the firm's successful IPO in 2020. Dr Kawas highlights five clinical trial advancements that emerged in 2024.

The FDA's Drug Development Cycle

During her tenure at Athira, Dr Leen Kawas guided several drug candidates through their respective drug development cycles. In each case, she was an active participant in clinical trial design. For reference, Dr Leen Kawas details the multi-step drug development process.

The United States Food and Drug Administration (FDA) requires every drug to undergo a rigorous evaluation. During the FDA drug approval process, each step must be successfully completed before the company can proceed to the next one.

Collectively, this exhaustive research and testing process must demonstrate that the drug's benefits outweigh its risks when used for a specific condition. In other words, the drug must be shown to be "safe and effective" before being approved for public use.

The FDA's Multi-Step Drug Approval Process

- Company Develops the Drug and Seeks FDA Approval
- Animal Testing Takes Place to Determine Potential Serious Harm
- Company Transmits an Investigational New Drug (or IND) Application
- Company Begins 4-Phase Clinical Trials and then Sends Study Reports
- Company Submits a New Drug Application (or NDA)
- The FDA Evaluates the Drug's Packaging and Labelling
- The FDA Inspects the Drug Manufacturing Facilities
- The FDA Issues an NDA Approval or a Response Letter
- Company Sends Serial Drug Safety Updates to the FDA

The FDA’s Two-Pronged Clinical Trial Initiative

Dr Leen Kawas has long advocated for more diversity in clinical trials' patient cohorts. She also believes trial participants should receive better support from clinical trial managers and support teams. Dr Kawas highlights two complementary FDA initiatives that will drive significant progress on both fronts.

Trial Participant Diversity

The FDA is strongly prioritising clinical trials' diversity for two reasons. First, a trial with participants from diverse backgrounds more accurately reflects changing United States demographics. In addition, improved trial diversity drives better data quality. This enables the FDA to make a more informed drug approval decision.

The FDA now requires clinical trial researchers, sponsors desiring late-stage trials, and other stakeholders to submit a trial participant diversity plan. Dr Leen Kawas noted the FDA's expanded diversity parameters.

- Age Diversity: Increased Elderly Patient Recruitment
- Gender Diversity: Higher Number of Female Participants
- Socioeconomic Status Diversity: More Participants from Lower Brackets
- Geographic Area Diversity: Better Geographic Distribution of Participants

Trial Participant Protections

The FDA strongly advocates for inclusion of patient views in all clinical research phases. Towards this end, the agency holds patient listening sessions and patient-focused drug development informational events.

In both cases, the FDA invites patients to offer insights on living with a specific condition. The agency also encourages patients to voice their opinions on clinical trial participation.

On a related note, the FDA endeavours to streamline the participants' informed consent process. Specifically, the agency is pursuing strategies to make this often complex information easier to understand.

Patient Concierge Services Integration

Dr Leen Kawas emphasised that patient recruitment and retention present a major barrier to success in clinical trials. In a highly strategic move, trial sponsors and contract research organisations (or CROs) have begun to consider patients' preferences, needs, and barriers to participation.

To address trial participants’ concerns, emerging patient concierge services now handle patients’ clinical trial participation logistics. This extra support also greatly reduces the intimidation factor. As a result, patients and their families become more comfortable with the trial process.

Five Types of Patient Concierge Services

- Itinerary Coordination (includes flight and/or rail tickets, ground transport, and lodgings)
- Longer-term Relocation and Housing Assistance
- Passport and/or Visa Coordination
- Applicable Translation Services
- Reimbursements for Incidental Expenses

Strategic Decentralised Trials' Expansion

During the COVID-19 pandemic in 2020, study sponsors and contract research organisations were compelled to comply with ever-changing lockdown regulations. Companies have turned to decentralised clinical trials (or DCTs) to keep existing studies moving and initiate new ones. These studies incorporated telemedicine and home care to achieve clinical trial goals.

In 2024, most study sponsors have returned to dedicated clinical trial facilities. However, organisations are taking a second look at the DCT structure to potentially reduce under-enrolments and high dropout numbers. Without hard-to-reach central trial sites, patients who could not otherwise participate could access potentially useful treatments.

Dr Leen Kawas noted that future studies may integrate DCTs' features with conventional trials' patient support services. Telemedicine and home care would mean substantially fewer clinical site visits. Concurrently, patients would receive targeted treatments in a controlled clinical setting. With fewer demands on patients and their caregivers, the odds of participant retention would likely increase.

Digitisation of Trial Experiences

Increased use of digital technology enables study sponsors to realise improved efficiencies during clinical trials. Telemedicine and wearable devices enable greater patient connectivity. In addition, trial sponsors and contract research organisations can now digitise participant data, feedback, and treatment administration.

Three Key Components of Digitised Trial Experiences

Dr Leen Kawas noted that digitised business operations are standard in many industries. Three key digitised components will foster improved efficiency and higher accuracy rates during clinical trials.

- Streamlined Engagement via Study Sponsor, Clinical Site, and Patient Portals
- Higher Trial Efficiency and Accuracy via Better Information Flow and Integrated Data Management
- Transparent Financial Transactions via Advanced Payment Processing Functionalities

The FDA Discusses Clinical Research’s Future

The Food and Drug Administration said future clinical research must use more efficient methods of obtaining required evidence. Two suggested methods are expanding clinical trial access and gathering information via standard clinical practice.

In addition, the FDA expects new clinical research technologies and methodologies to drive faster introduction of new patient therapies. The FDA also plans to integrate artificial intelligence (AI) and machine learning into its evaluation process.

To inform more effective clinical trial design, the Food and Drug Administration will continue to encourage patient and caregiver perspectives. Dr Leen Kawas emphasised that the FDA's leadership, combined with emerging patient-centric initiatives, will ultimately drive a more streamlined introduction of patient therapies.

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