CRITICAL PATH INSTITUTE

How NAMs are Redefining Drug Development

The newest episode of the Critical Path Institute Podcast features C-Path CEO and host Klaus Romero, as well as C-Path Interim Executive Director of the New Approach Methodologies Developer Coalition (NAMs-DC), Graham Marsh. The duo engages in a discussion centered around the evolution of translational science bridging preclinical research and human trials.

Graham emphasizes the importance of defining the “context of use” for each NAM, specifying the unmet need in regulatory science or drug development that it addresses. C-Path is taking a proactive approach to translating NAMs into wider adoption with formation of NAMs-DC, a pre-competitive forum to harmonize evidentiary standards and promote adoption.

Additional partnerships highlighted include a collaboration involving partners like Advanced Research Projects Agency for Health and FDA to integrate NAMs into regulatory decision-making from early development stages, and the recent launch of the National Center for Accelerating Cures (NCAC) to provide critical external validation and regulatory expertise for NAM developers. Looking ahead, Graham envisions NAMs becoming standardized, mainstream methods that improve drug development efficiency, reduce animal use, and enhance predictive accuracy. Data sharing and ecosystem integration remain key challenges but also immense opportunities for the field’s growth.

Key Insights

- **NAMs redefine preclinical testing beyond traditional assays.** By integrating complex 3D tissue models and computational simulations, NAMs enhance biological relevance compared to 2D cultures or animal models, which often poorly predict human responses.

- **The NCAC represents an ecosystem approach to NAMs validation and scaling.** By offering regulatory expertise, laboratory capabilities, and venture ecosystem support, NCAC enables NAMs developers to build robust evidence for regulatory applications, accelerating these innovative tools’ transition to standard use.

- **Mimicking human organ function with micro-physiological systems is a game changer for translational science.** Technologies like organ-on-chip can replicate organ-specific physiological conditions (e.g., blood flow, shear stress), recapitulating complex cell interactions and functions that animal or standard cell culture models cannot capture.

- **The concept of “context of use” bridges scientific innovation with regulatory acceptance.** NAMs must be tied to a clearly defined unmet need or regulatory question to build the right evidence package. This triad of developers, pharmaceutical scientists, and regulators facilitates qualification, ensuring NAMs are fit-for-purpose and not misapplied.

- **Pre-competitive collaboration accelerates NAMs qualification and adoption.** C-Path’s NAMs Developer Coalition exemplifies how companies can share standards, validation data, and advocacy efforts, overcoming the regulatory unfamiliarity of NAMs and driving widespread uptake in drug development pipelines.