Drug and Device Development Services

Drug and Device Development Services helps move discoveries at the lab bench into clinical testing to develop novel approaches to prevent and treat pediatric disease.

The Food and Drug Administration (FDA) regulatory review process for clinical trials is complex. Drug and Device Development Services (DDDS) guides Nationwide Children's Hospital investigators through the regulatory landscape and provides a streamlined and uniform approach to translating pre-clinical studies into human clinical trials.

DDDS works side-by-side with Clinical Research Services to assist with clinical design and regulatory submissions and with the Office of Research Compliance and Integrity to ensure compliance with all institutional, state and federal laws and regulations.

DDDS is a resource within The Research Institute at Nationwide Children's Hospital in the Center for Clinical and Translational Research and is available to all medical faculty and investigators.

SERVICES

Pre-Clinical Development

DDDS offers consultation with investigators to discuss specific pre-clinical development plans, focusing on tasks needed to efficiently move the drug or device to the clinic according to FDA guidelines. We can also provide insight into associated costs and complications that you might anticipate during the process.

Typical pre-clinical consulting services include:

- Proof-of-concept
- Manufacturing
- Toxicology
- Animal models
- Analytic methods
- Pharmacokinetics/biodistribution
- Biomarker assay development and validation

FDA Interactions and Applications

DDDS offers consultation to investigators on the scientific information required to support an Investigational New Drug or Device application to the FDA. This includes characterization of the product, animal models of safety or efficacy, or toxicology. In addition, we will consult on the content of the IND application and FDA interactions in general. This support currently includes review of pre-pre-IND, pre-IND and IND applications, annual reporting and end-of-study phase interactions with the FDA.

Typical IND/IDE application services include:

- Format of type C (pre-pre-IND/IDE) meeting applications and interactions
- Format of type B (pre-IND/IDE) meeting applications and interactions
- Outline and format of IND/IDE application and interaction
- Study protocol and design
- Maintenance of the IND/IDE (annual reports, safety reports, final reports, etc.)

Contact Drug and Device Development Services

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