

DRAFT National Institutes of Health (NIH) Pediatric Device Development Plan

Major Topics
June 2008

- Catalog of current device projects that are NIH funded from each of the Institutes and programs
Rationale: A coherent and uniform summary provides a snapshot of the scope and focus of currently funded research that can inform the topic of unmet needs as well as areas of activity.
Status: Information survey complete; undergoing formatting and high-level analysis.
- Listing of funding programs that target either pediatrics or devices, including Small Business Innovation Research (SBIR) grants and a catalog of available programs with value-added commentary on device expectations
Rationale: A coherent and uniform summary provides a snapshot of current funding opportunities for pediatric device development.
Status: Catalog is under preparation.
- Description of available infrastructure for pediatric research that would support device development, including not only NIH but also other resources from other federal agencies and additional funding sources
Rationale: A coherent and uniform summary provides a snapshot of current infrastructure opportunities for pediatric device development.
Status: Catalog is under preparation.
- Summary of NIH ethical policies related to enrolling children in clinical trials based on NIH policy—NIH policy has requirements with regard to compliance with the protections under Title 45 Section 46 of the Code of Federal Regulations for federally funded research and to compliance with the protections under Title 21 Section 50 of the Code of Federal Regulations for Food and Drug Administration (FDA) regulated products. There are variations in the two sets of regulations that must be addressed when both sets of regulations apply. Providing guidance on compliance with both sets of regulations will be important in facilitating research.
Rationale: Regulatory compliance is necessary and can be facilitated by guidance on concurrent compliance with multiple regulations.
Status: Guidance document is in preparation.
- New approach to evaluating award applications and to setting expectations/assessing outcomes—The plan calls for development of a model that would permit, following the completion of initial proof of concept studies, robust evaluation of a proposal for private or public-private funding. The proposed plan needs to identify the key information elements for transition from early phase studies to activities leading to marketing development and must systematically include not only planning for these stages in an application but also for development and delivery of those information elements in a final study report. Examples of the type of information are:
 - Summary of intended use with scientific proof of concept
 - Description of other products with similar intended use
 - Expected intellectual property status and issues

- Epidemiology of the disease or condition with high level market analysis
- Scale up or manufacturing plans with anticipated challenges and general estimate of costs
- Anticipation of planned clinical studies for safety and either demonstration of efficacy or strategy to pursue a premarket submission (510(k)) to the food and drug administration

Any publicly funded project would be expected to meet the scientific objectives as well as the identified business development objectives before it can be considered feasible and of sufficient priority to merit funding. The funding review process would require supplementation to ensure accurate and objective evaluation of proposed plans; the project evaluation process would also require supplementation to properly assess all components of the completed package. Successful completion of the project package would allow robust evaluation for the likelihood for further development.

Rationale: *The path from concept to product can be supported if framed by necessary systematic and appropriate acquisition of information. Establishing a formal mechanism to acquire and assemble the information will expedite the process and allow timely assessment.*

Status: *Public comment is sought on the concept.*