Subcommittee on Medical Technologies (Devices and Diagnostics)

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NCATS ADVISORY COUNCIL MEETING

JANUARY 15, 2015

NCATS

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NIH Medical Device Portfolio Analysis

Bill Heetderks and Todd Merchak, NIBIB

Background:

- No NIH Research, Condition and Disease Categorization (RCDC) system code for “medical devices” exists
- Medical device category including subcategories was drafted
- NIH grant database coded using the draft category
- Trans-NIH assessment of reasonableness of the framework

Subcategories of Medical Devices

Assistive	Diagnostic	Imaging	Implant	Surgical
• Brain computer interface • Cochlear implants • Neuro-stimulation • Prostheses • Rehabilitation	• Assays • Biosensor • ECG,EEG,MEG • In-vitro diagnostics • Monitoring device • Microfluidics • Point of care	• Detector • Endoscopy • Medical imaging • MRI • Optical • PET/SPECT • Ultrasound • X-Ray	• Artificial pancreas • 3D Tissue printer • Biocompatible materials • Catheters • Stents • Ventricular assist device	• Ablation • Biopsy • Deep brain stimulation • Laparoscopy • Radiation therapy • Ultrasound therapy

Conclusions of NIH Portfolio Analysis

- Diagnostic and imaging account for 60% of the grants; the other three categories 40%
- Five Institutes (NCI,NIBIB,NHLBI, NIGMS and NINDS) support 50% of the grants
- Roughly equal split between grants for pre-clinical development & testing and clinical testing
- Diversity of medical devices research across the translational spectrum supported by NIH
- Medical technology accounts for one third of all SBIR grants

NCATS Opportunities with Medical Technologies

- Address systemic issues in development and implementation of medical devices for all applications including diagnostics
- Enhance collaboration and cooperation in medical device research among stakeholders
- Education and training of workforce
- Define knowledge gaps and resource requirements

Recommendations

- Convene experts and stakeholders in workshops and conferences on specific challenges in medical devices, e.g.,
  - Legal and IP
  - Reimbursement
  - Business plans, models and market analysis
  - Clinical need, usability and validity
  - Team science of medical device collaborations
  - Engage new communities in device development

Recommendations

- Engage all stakeholders, (e.g., academic, commercial, patients, payers, research and regulatory agencies) in addressing gaps in knowledge and resources for investigators/clinicians/ engineers (and trainees) to move products from discovery to patients:
  - Understand CTSA landscape for training and educational resources in medical device development
  - Learn from SBIR's new commercialization training programs (Lean, I-Corps, other commercial programs)
  - Provide advisors/mentors/staff with expertise in regulatory, reimbursement and other commercialization strategies

Recommendations

- Addressing gaps in knowledge and resources (continued):
  - Involve other programs at NIH (e.g., NCI, NHLBI, NIBIB) and other government departments (e.g., FDA, CDC, DARPA)
  - Involve Pharm/biotech/VC (PBV) community for guidance and for identifying opportunities
  - Include new industry entrants in the Medical Devices field.