Subcommittee on Medical Technologies (Devices and Diagnostics)

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NCATS ADVISORY COUNCIL MEETING
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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

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