Harnessing the Discovery Engine of NIH to Maximize Translation

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I was asked to address:

• How does FNIH identify and prioritize new projects?
• How does FNIH ensure that the key stakeholders, national and international, are included in new partnerships?
• How does FNIH avoid duplicating efforts?
• Does FNIH address intellectual property concerns on a case-by-case basis?
• What are the benefits of fostering collaboration between the US and the EU?
About FNIH

Purpose:
- To support the NIH in its mission; and,
- To advance collaboration with biomedical researchers from universities, industry and nonprofit organizations.

Structure:
- 501(c)(3) non-profit organization created by the US Congress;
- Independent Board of Directors;
- NIH Director and FDA Commissioner ex-officio Board Members.

Highlights:
- Raised >$700 million since 1996;
- Supported >400 projects, ~100 currently active
  - research partnerships, scientific education/training, conferences/events, and capital programs
- 94 cents of every dollar spent directly supports programs
- 4-star Charity Navigator rating for past six years
Identifying Projects - In a nutshell:

1. **EC/SC, RFA/RFP or External Submission**
   - Initial Concept

2. **Steering Committee**
   - Approved Project Concept
   - Scientific merit
   - Pre-competitive
   - Feasibility
   - FNIH conducts funding scan

3. **Steering Committee/Project Team**
   - Project Plan
   - Protocol
   - Resources
   - IP
   - Data sharing/distribution
   - Timelines/milestones
   - Budget
   - Human subjects
   - Privacy
   - Legal review

4. **Executive Committee**
   - Approved Project
   - Final QA/QC
   - Contracts
   - FNIH secures final project funds

5. **FNIH & Multi-stakeholder Project Team**
   - Launch
   - Project execution
   - FNIH manages project
Ensuring participation of key stakeholders:

- FNIH proactively seeks participation of key stakeholders:
  - Good practice, good business, good sense.

- FNIH serves as the convener and neutral third party:
  - This allows for inclusive governance of projects.

- Scouting through:
  - Direct engagement at high levels of government, industry and non-profit partners nationally and internationally;
  - Broad outreach to private sector (including foundations) leaders through our Partnership Development group;
  - Open, web-based solicitation for grants, contracts;
  - Collaboration with organizations having a global mandate, such as the Bill & Melinda Gates Foundation, Wellcome Trust and various PPPs.

- For major research partnerships:
  - Scientific advisory boards,
  - Project teams,
  - Steering committees,
  - NIH,
  - Others
Benefits of collaborating between US/EU: Let me count the ways....

– Increased breadth and complexity of knowledge, from basic biology to clinical practice, requires multiple players → matrixes of expertise;

– Shared expertise, from multiple parties, is imperative to address precision medicine, "big data" challenges and streamline drug development;

– Enhances/leverages resources: human, technological and financial;

– Avoids duplication;

– Helps bring innovation to patients.