

NAS Workshop: Measuring Impacts of Federal Investments in Research

Medical Device Industry Perspectives

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Key observation: Devices Differ from Drugs

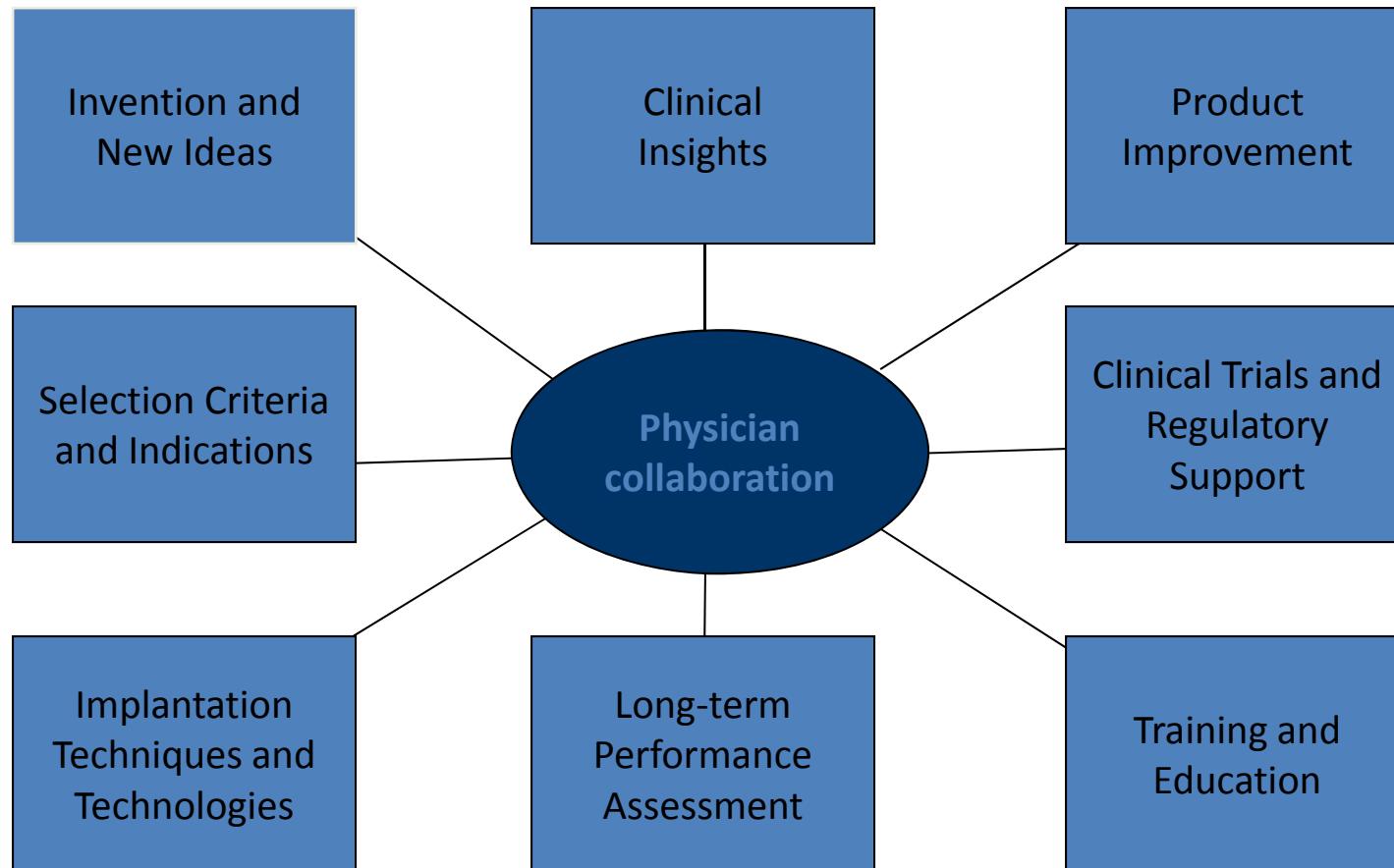
Devices	Drugs
Direct mechanism of action – Readily apparent response	Indirect mechanism of action – Metabolites, liver inactivation
Site/organ-specific therapy	Systemic treatment
Uniform patient response to therapy (generally)	Variable patient response – Dosing – Side-effects, toxicity
High initial cost	Costs accumulate over treatment
Automatic therapy	Dependence on patient compliance
Progressive efficacy improvement	Efficacy static
Next-generational cost-effectiveness improvement	Cost-effectiveness relatively constant

R&D Process for Devices and Drugs Differ

Drugs are discovery based.
In-house emphasis

Devices are engineering based.
Many external dependencies

Physician*-industry collaboration plays a critical role in medical device innovation.



* In many instances these are academics involved in NIH grant supported research.

Federal investments have essential impacts.

Medical devices can result from funded programs

- Research grants that tease out a technology solution**
- Clinical research that solves an unmet need**
- Laboratory research that produces an innovation**

The majority of federal investments produce:

- underlying knowledge and understanding**
- enabling technologies**
- focused expertise**
- leading-edge infrastructure and instrumentation**
- feasibility demonstration**

Contributions are enabling and facilitating

Less visible but crucial impacts.

“Best practices” knowledge, expertise, resources:

- Add rigor to R&D process and manufacturing
 - Design controls**
 - Software validation**
 - Reliability**
 - Clinical trials paradigms**
 - Packaging engineering**
 - Manufacturing practices**
 - Vivariums**

Project Prioritization & Selection Considerations

Technology fit

Customer fit

Market opportunity

Time to market (aka regulatory pathway)

Final thoughts.....

R&D investments are not fungible.

Projects are difficult to resurrect once turned off.