

Science and the Medical Physicist in The Product Development Cycle

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July 27th, 2018



Disclosures

John Sabol is an employee of GE Healthcare.

The views expressed on this presentation are my own and do not reflect those of my employer.



"...it's unearthly, it's downright mystical."
Wilhelm Conrad Roentgen, November 1895



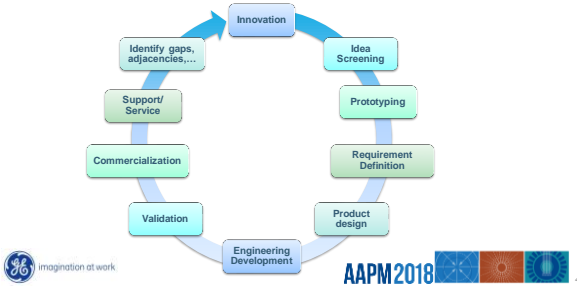
Nov. 1895



Edison's 'Vitascope' March 1896



The Product Development Cycle



Engineering Versus Science

Research and Development

Science and Engineering



The Engineer's Dilemma

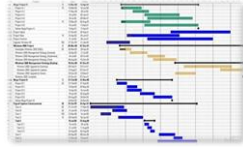
... Pick Two ...



Engineers – Two Possible answers



Yes



When



Scientists – Also two possible answers



Yes



No



Scientists – Also two possible answers

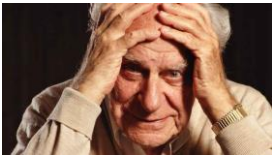


Yes*

* Until new observations provide evidence that the hypothesis or paradigm under which the decision was made are incorrect, then the answer may be no.

An answer of 'Yes' often only means that there is a reasonable probability that the answer of 'No' is unlikely given a random sample and that estimates of underlying distributions are correct.

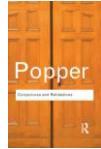




"Every genuine test of a theory is an attempt to falsify it, or to refute it."

... the scientific status of a theory is its falsifiability, or refutability, or testability.

Karl Popper, *Science as Falsification*, 1963



Goals for Corporate Research

Identify & address unmet clinical needs

- Disease states, departmental, or healthcare system needs
- Underserved or unique patient populations

Accelerate and focus innovation

- Identify new uses and better utilization of existing technology
- Explore new clinical and technical concepts

Drive clinical acceptance and optimization of new technology


- Generate data to support regulatory approvals
- Provide evidence for technology adoption



Continuum of Research Activities



Discovery Example:



Discovery
Technology development and innovation, disease-focused, exploratory concepts.

The use of open research calls and peer review to fund innovation

- Use the methods of scientific peer reviewed grant funding to select the best research plans for specific areas of innovation



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Development Example:



Development
Product Development, Safe & effective use and regulatory clearance.

Advanced iterative and model-based reconstruction for dose reduction in CT

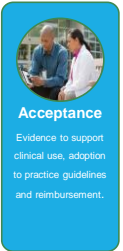
- Develop dose measurement methodology
- Quantify dose levels of standard of care
- Develop and utilize innovative ideal observer models to compare IQ and performance at different dose levels
- Define and guide use of these methods for regulatory clearance



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Acceptance Example:



Acceptance
Evidence to support clinical use, adoption to practice guidelines and reimbursement.

Tomosynthesis for detection of subtle hip fractures in the ED

- Can tomosynthesis reduce the use of MR or CT in patients with suspected hip fracture but negative x-ray?



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Expansion Examples:



SYNTAX III: CT imaging in Cardiac Care: CABG vs PCI - How to treat?

- A randomized trial using GE-Revolution CT and HeartFlow® FFRCT to study decision-making on the optimal revascularization treatment

Tomosynthesis for improved lung nodule detection:

- Define and lead a clinical trial for regulatory clearance for new intended use claims

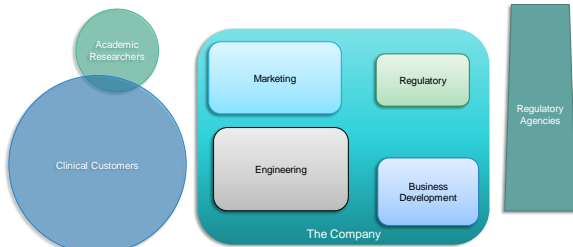


Medical Physicist: A multidisciplinary scientist

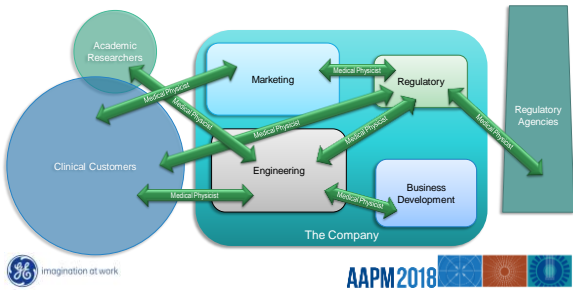
- Translate clinical problems into falsifiable problem statements
- Convert marketing desires into technical requirements
- Express clinical and technical specifications into marketable language
- Bridge the gap between academic and clinical research partners and business teams
- **Take Risks - ask the questions to which we do not know the answer**



Business Functions and Customers



Business Functions and Customers



The Babel Fish



The Hitchhiker's Guide to the Galaxy: Douglas Adams



Unique Role for the Medical Physicist



*Thank you for your attention,
and to many colleagues and
mentors for the education.*



