Imaging product development; from concept to a clinical device

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Disclosures
- Employee, Canon Medical Systems

Where does medical technology come from?
- I've got an idea for a new technology that would benefit patient care.
- I have an idea that could improve this product.
- Who thought it was a good idea to put this button here?
- I think an idea that could improve this product.
- Why did Vendor A make this product and Vendor B make that product?
Whose idea was this anyway?

**Product conception**

- Technology development ideas come from everywhere
- Users (customers)
- Market trends analysis
- Academia (research collaborations or independent)
- Focus groups
  - Internal ex: Clinical Trends
  - External ex: MAB
- Industry scientists (hey, what if we try this...?)
- Regulatory (FDA, etc.)
- Professional Organizations (AAPM, IEC, MITA, etc.)
- etc.

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Example

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Who decides if an idea is worth consideration for development?

**Vetting the idea**

- This is decided on by the R&D and business teams based on info from:
  - Market Needs (including all regions globally)
  - Clinical trends groups (internal)
  - Medical Advisory Boards (external)
  - Regulatory drivers

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MAB = Medical Advisory Board
Develop detailed product consideration documents

- Product Specifications
- Intended Use
- Costs considerations
- Priorities

Turning an idea into reality

Mind Map to determine specifications

Do we really want to commit to this?

Vetting the idea (again)

- Reassess the proposal with business plan.
- Development cost (time and $)
- Opportunity cost: What other projects do we have to delay to develop this technology?
- Supplier considerations
- Business Impact (revenue, training costs, etc.)
- Clinical/Regulatory risks
  - FDA related risks (e.g., MyoCTP)?
  - Reimbursement considerations (can customers charge for it?)
Time to get started!

- Engineering Development
  - hardware vs. software
  - FDA Class I, II, or III device
  - etc.


Design Control

Clinical Validation

- Design Control is complete
- Regulatory product clearance
- Product is complete!

- Not done yet!
  - Clinical Validation studies
  - Economic impact studies
  - Use examples
  - Marketing materials/ brochures
  - White papers
  - etc.

Thank You