



The Move to Connected Devices

Key elements to consider in product design

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Battelle's mission: To translate scientific discovery and technology advances into societal benefits



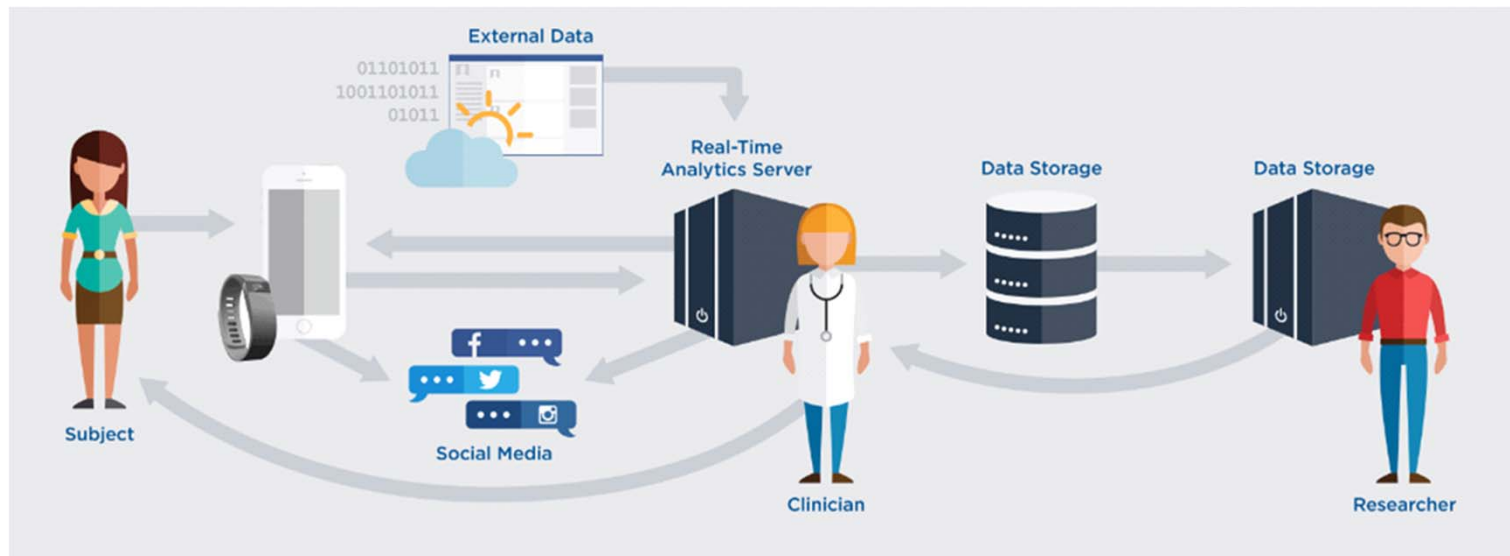
Gordon Battelle, Founder

- Nonprofit, charitable trust formed in 1925
- Profits reinvested in science & technology and in charitable causes, making the world better for generations to come
- Knowledge, talents and resources applied to help our customers achieve their most important goals

Getting Started

So you have made the decision for a connected drug delivery device...

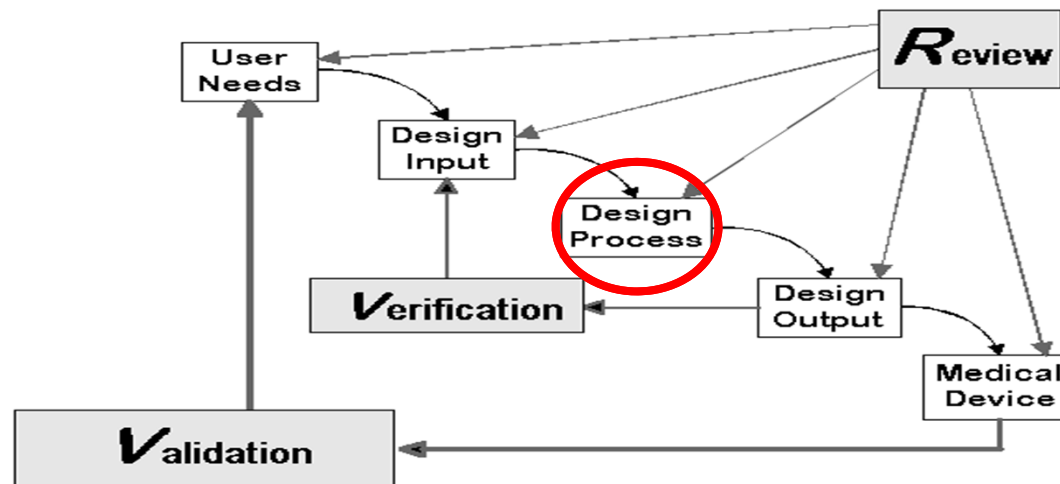
- Identified need for connected
- Defined user and use cases
- Mapped complete picture for what to do with data
- Ready to initiate Product Development Process



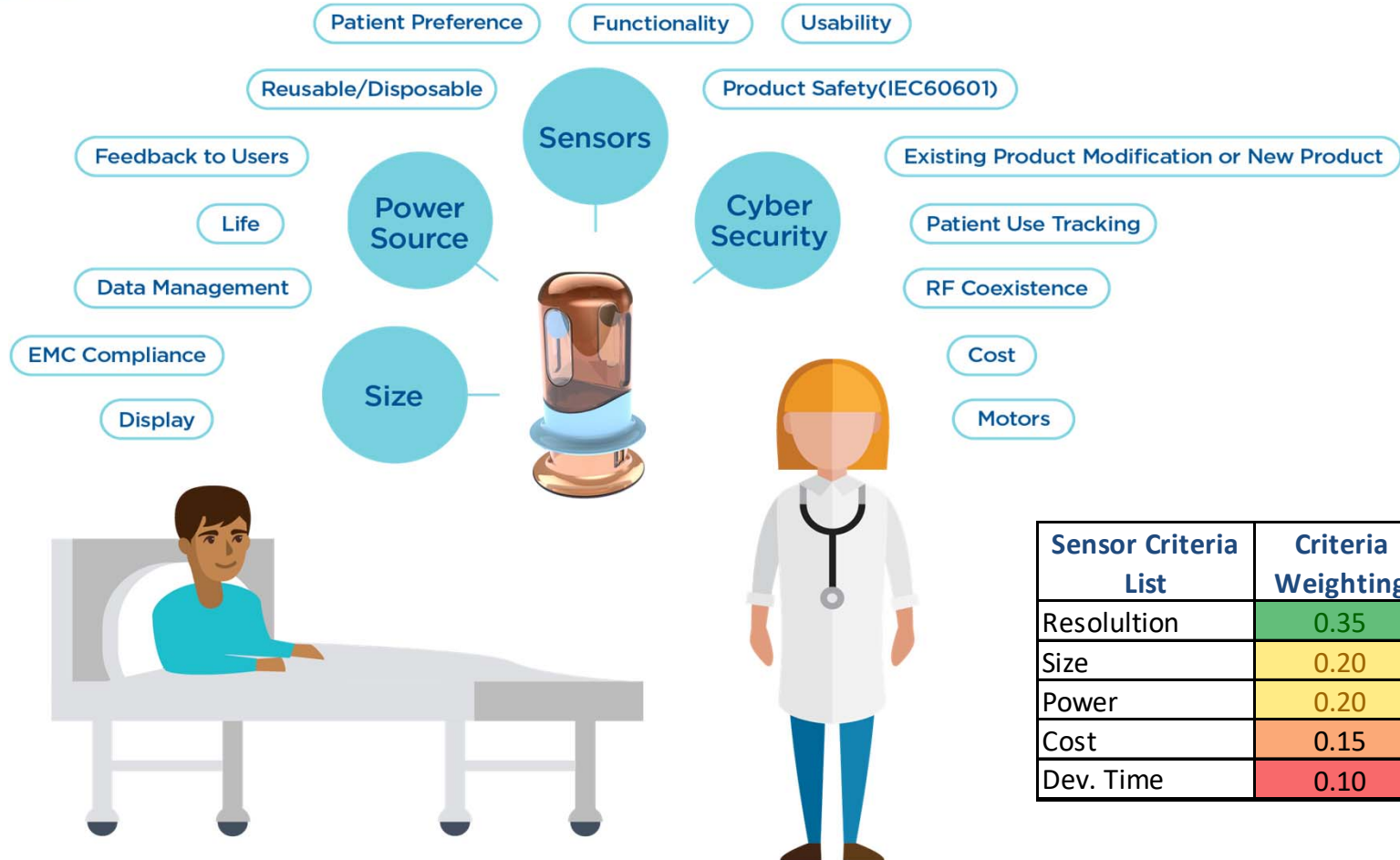
What elements should be considered in the device design?

Product Development Process

- Translate user needs, user feedback, marketing input, and performance needs into testable product requirements
- Execute design activities continuing to update product risk assessment
- Generate drawings and documents to support design
- Confirm design performs to requirements
- Confirm device design meets the needs of the user
- Review progress during each stage for team alignment before advancing



Considerations for a Connected Drug Delivery Device Design

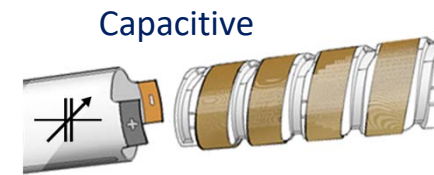
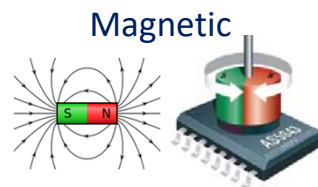
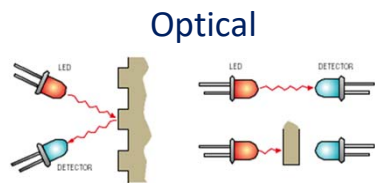


Sensor Criteria List	Criteria Weighting
Resolution	0.35
Size	0.20
Power	0.20
Cost	0.15
Dev. Time	0.10

- Define parameters for consideration
- Involve key stakeholders and prioritize based on needs

Sensors

- What is being sensed?
 - Dose delivered, temperature, device contact with patient, etc...
 - What are the moving parts?
- Is design add-on to existing device or new device?
 - Existing device: Establish constraints, identify components that can be leveraged
 - New device: Drive design to what is truly needed and adds value
- What are the key factors in identifying the correct sensor implementation?
 - Identify available sensor options
 - Identify key performance parameters: Resolution, Power, Timing, etc...
 - Identify external factors that could impact functionality



Cybersecurity

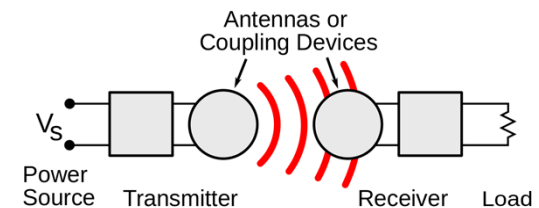
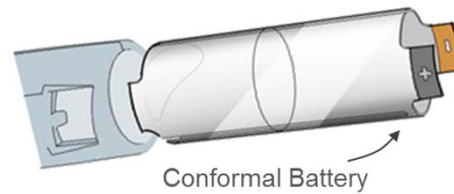
- What is the impact of **Confidentiality**?
 - Is there information in the system that must remain secret?
 - Protected Health Information, Intellectual Property
- What is the impact of **Integrity**?
 - Is there information or functionality in the system that must remain untampered?
 - Diagnostic algorithms, treatment configuration, serial number, expiration date
- What is the impact of **Availability**?
 - What pieces of the system must always remain available?
 - Therapy functionality? Bluetooth connection?



Power

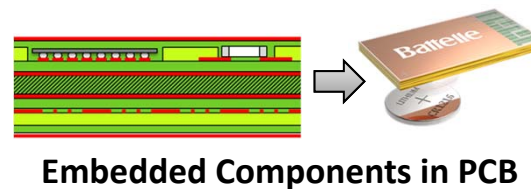
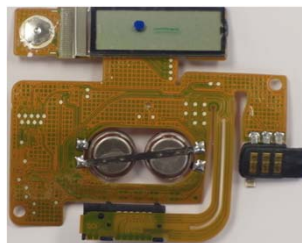
- Power source selection considerations
 - Power budget:
 - # sensors, type of sensor, monitoring of sensor, data transmission timing, data range, device power activation
 - Product life requirements
 - Form factor limitations
 - Integration of power source - External module or internal
- What power technology will be used?
 - Battery – rechargeable, replaceable, disposable
 - Energy Harvesting – real-time or energy storage capacitor required

Power			
	Optical Sensor	Magnetic Sensor	Capacitive Sensor
Optical Sensor	X	Optical Sensor is Worse Than to Magnetic Sensor	Optical Sensor is Worse Than to Capacitive Sensor
Magnetic Sensor	Magnetic Sensor is Better Than to Optical Sensor	X	Magnetic Sensor is About Equal to Capacitive Sensor
Capacitive Sensor	Capacitive Sensor is Better Than to Optical Sensor	Capacitive Sensor is About Equal to Magnetic Sensor	X



Size

- Additional functionality over a traditional mechanical injection device may make the device larger, but how much?
- Understanding and Evaluating Usability
 - Things to evaluate that can drive the design:
 - Size, weight, forces, quality of contact with patient for injection, buttons, thumb reach, displays and controls, demographics
 - Methods: Models, formatives studies, contextual research
 - Understand storage and general handling of device beyond the injection
- Size Impacts
 - Sensor Implementation, Displays and Controls, Power Source, PCB



Making the Key Design Decisions

- Calculate weighted priority with direct comparison of criteria
- Compile results and evaluate via summary table

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Options \ Criteria	Criteria					
	Resolution	Size	Power	Cost	Dev. Time	Relative Value
Optical Sensor	0.256	0.006	0.006	0.050	0.073	0.39
Magnetic Sensor	0.089	0.097	0.097	0.004	0.025	0.31
Capacitive Sensor	0.005	0.097	0.097	0.096	0.001	0.30

Summary

- Final design must meet the expectations of the users for both ease of use and performance to be successful
- It is important to understand the tradeoffs to achieve user and performance needs
- Key technical design criteria with a higher level of criticality for a connected drug delivery device include:
 - Sensor Selection
 - Cybersecurity
 - Power
 - Size
- Evaluate key design options using a structured process such as trade-off matrix
- Throughout development, review safety, performance and program risks to ensure the design continues to meet the needs

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It can be done

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