



Medical Device Interoperability

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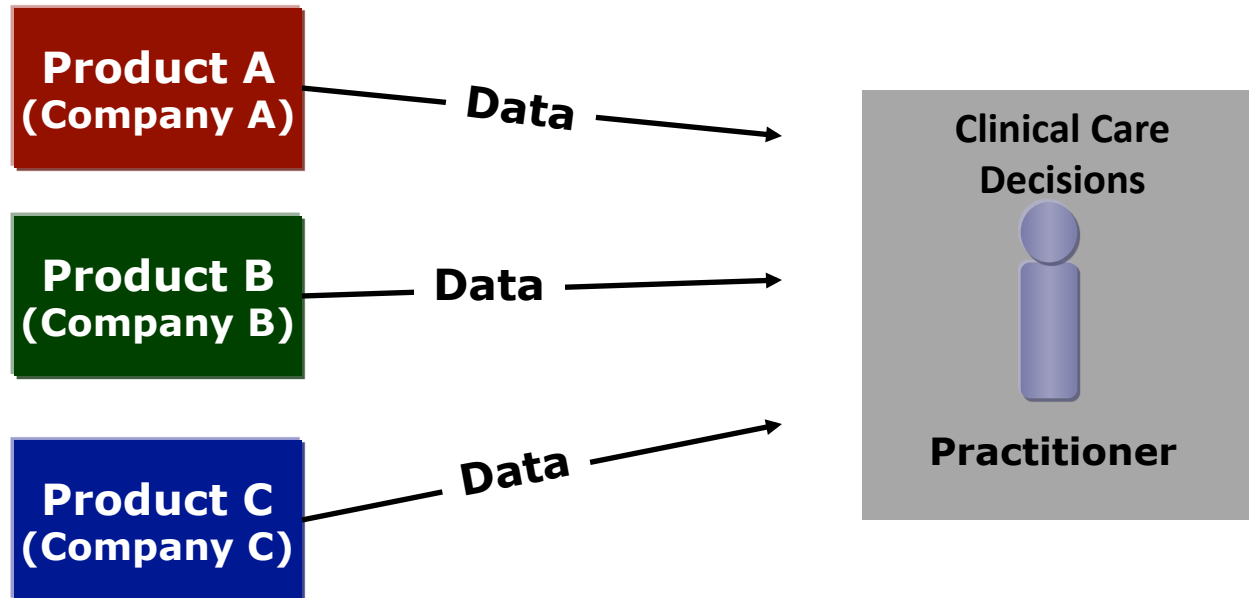
Interoperability is everywhere

We are surrounded by “plug-and-play” products and services:

- Computers connect to the web and deliver services.
- Financial systems are globally interoperable.
- We can design and control multimedia environments at home.
- We share files across platforms, including photographs using JPEG and documents using PDF.



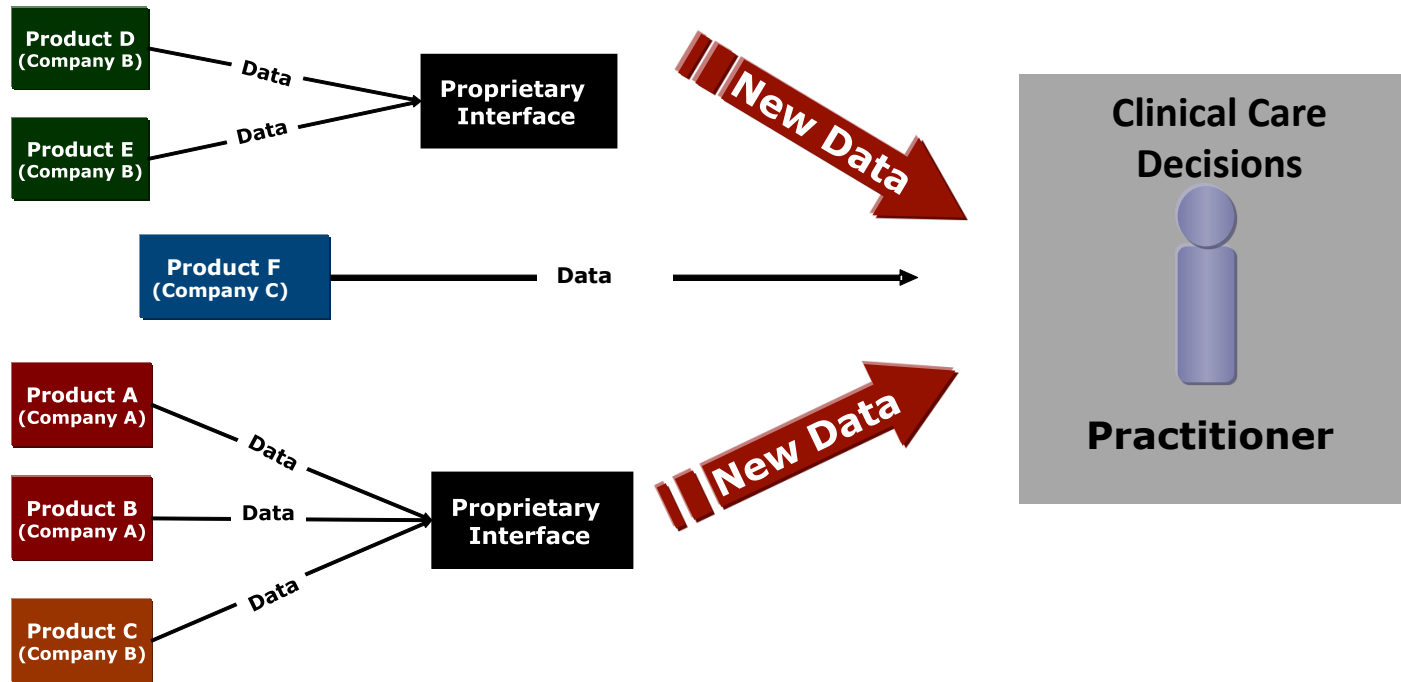
Non-Integrated Clinical Environment



- Devices from multiple manufacturers in standalone configurations
- Practitioner integrates “raw” data from multiple devices



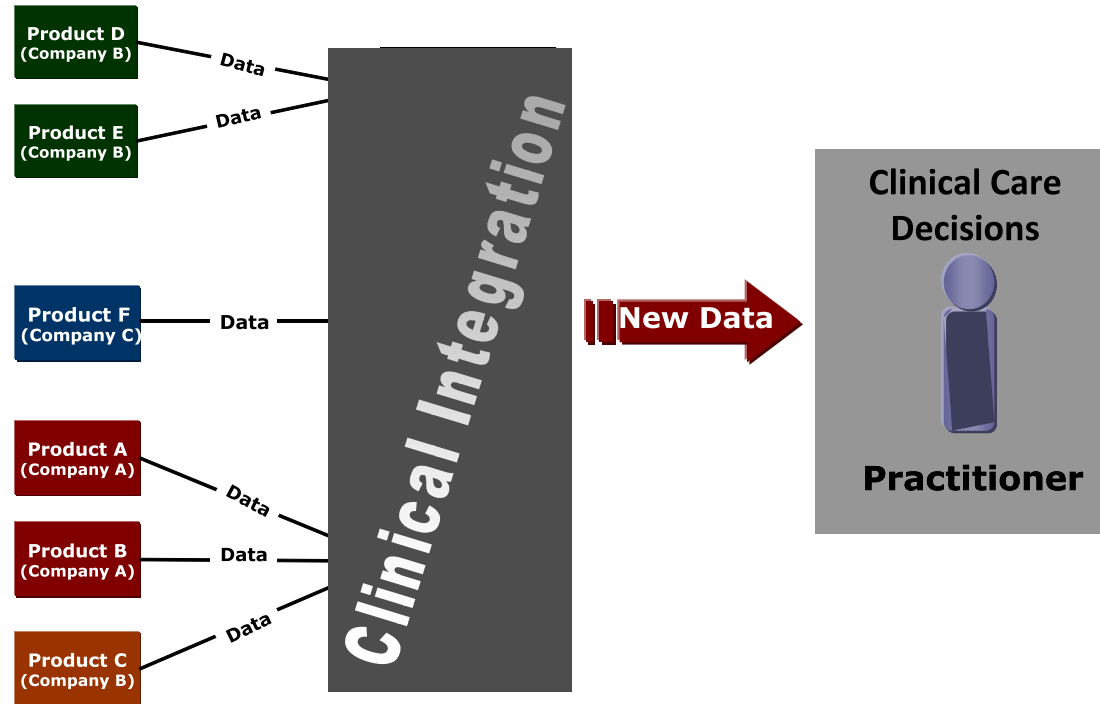
Partially Integrated Clinical Environment



- Some devices are integrated using proprietary protocols
- Practitioner integrates “raw” and analyzed data from multiple devices or device systems



Interoperable Clinical Environment



- Cross-manufacturer devices and device systems
- Integrated Clinical Functions: “Plug-and-play” devices and device systems connected through an infrastructure that includes integrated safety features
- Integrated Knowledge: Practitioner gets all information through a single interface



Types of Clinical Impact

- Patient centric device selection
- Increased patient accessibility to device-based care
- Patient centric safety interlocks
- Improved Quality Assurance
- Optimized patient-centric device configurations
- Optimized configuration management and protocols



The Challenge

- **How to assure safety and effectiveness?**
- **What tools need to be developed?**



Issues to be examined

- **Clinical**
- **Engineering**
- **Risk**
- **Management**



Clinical Issues

- **What clinical scenarios could make use of medical device interoperability?**
- **Are there clinical scenarios that would not be appropriate?**



Engineering Issues

How should medical device interoperability be defined?

- Architecture
- Components
- Interfaces
- Functional requirements
- Performance requirements



Risk Issues

What are the risks associated with medical device interoperability and “systems of systems” composing medical devices?

- Risk models for interoperable systems



Management Issues

Who are the responsible parties and what is their role in:

- Design
- Building
- Maintenance
- Improvement
- Development and dissemination of standards and best practices

