

# UDI Challenges

**September 14, 2016**

**RAPID Think Tank**



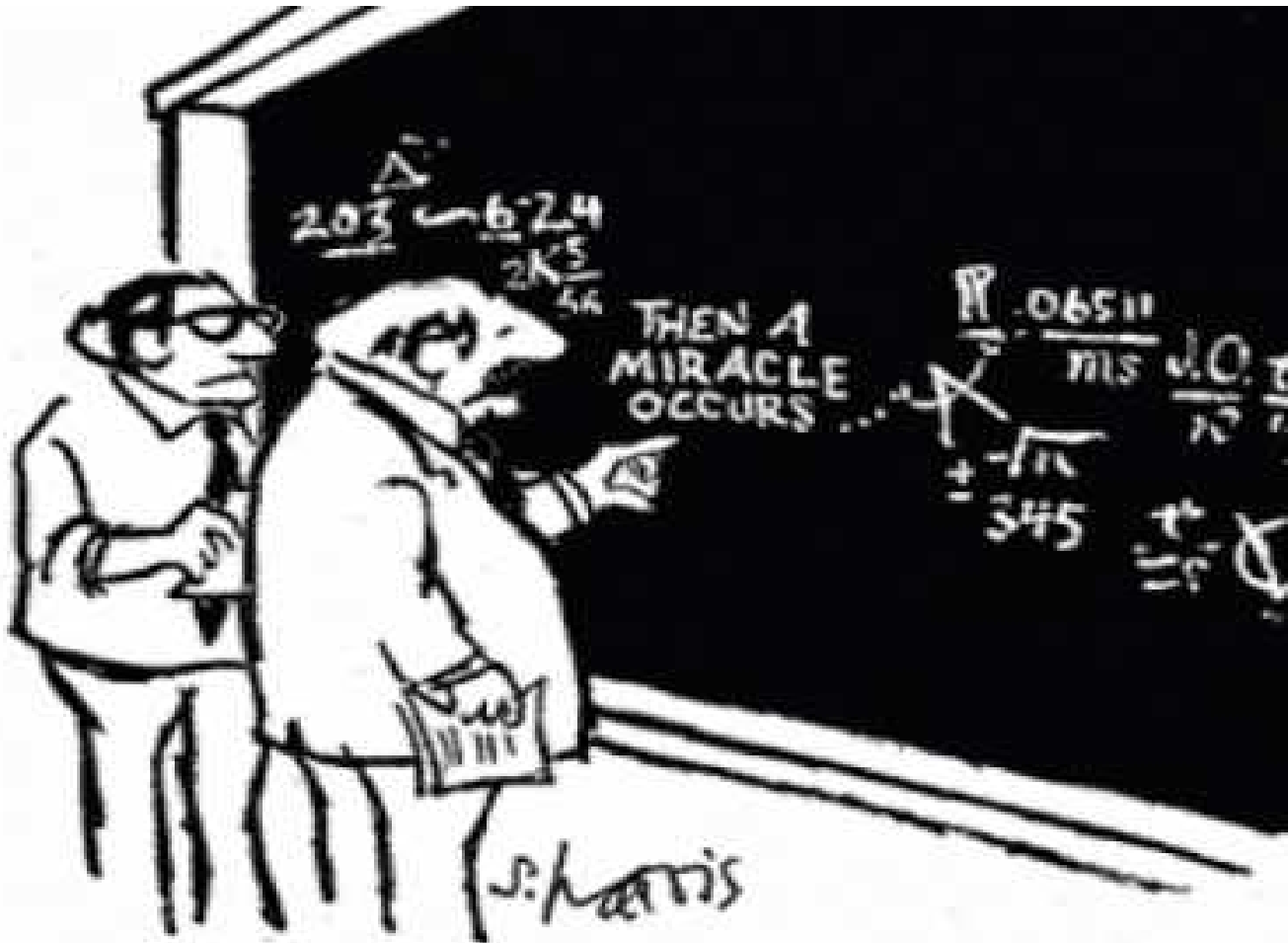


# How do we leverage device and clinical data for device evaluation?

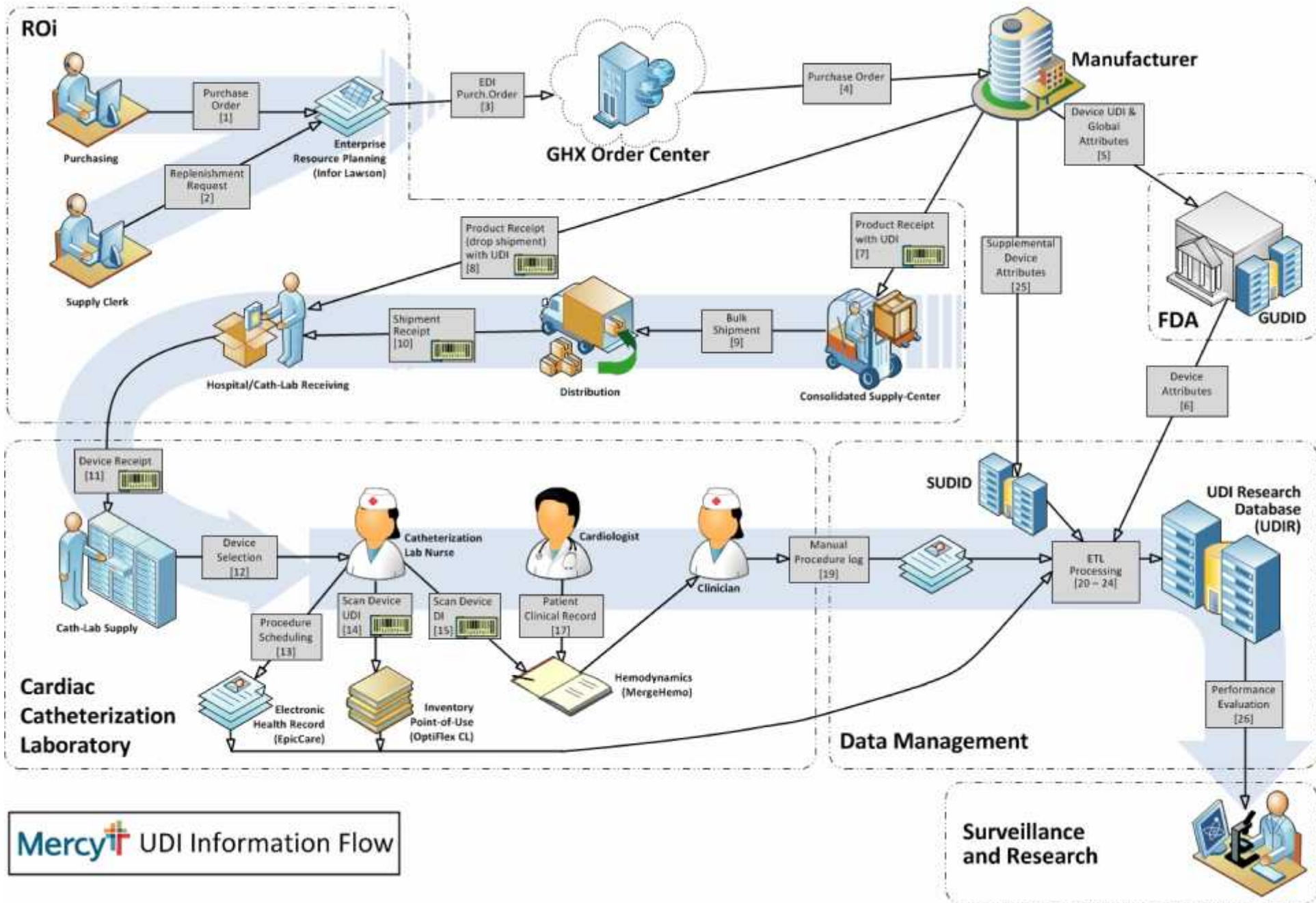
1. **Link the device with the patient.**
2. **Link clinically meaningful attributes to the device.**
3. **Combine device/attribute data with clinical (EHR) data in a database for effectiveness and safety analyses**

# UDI: The Key to Knowledge





"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."



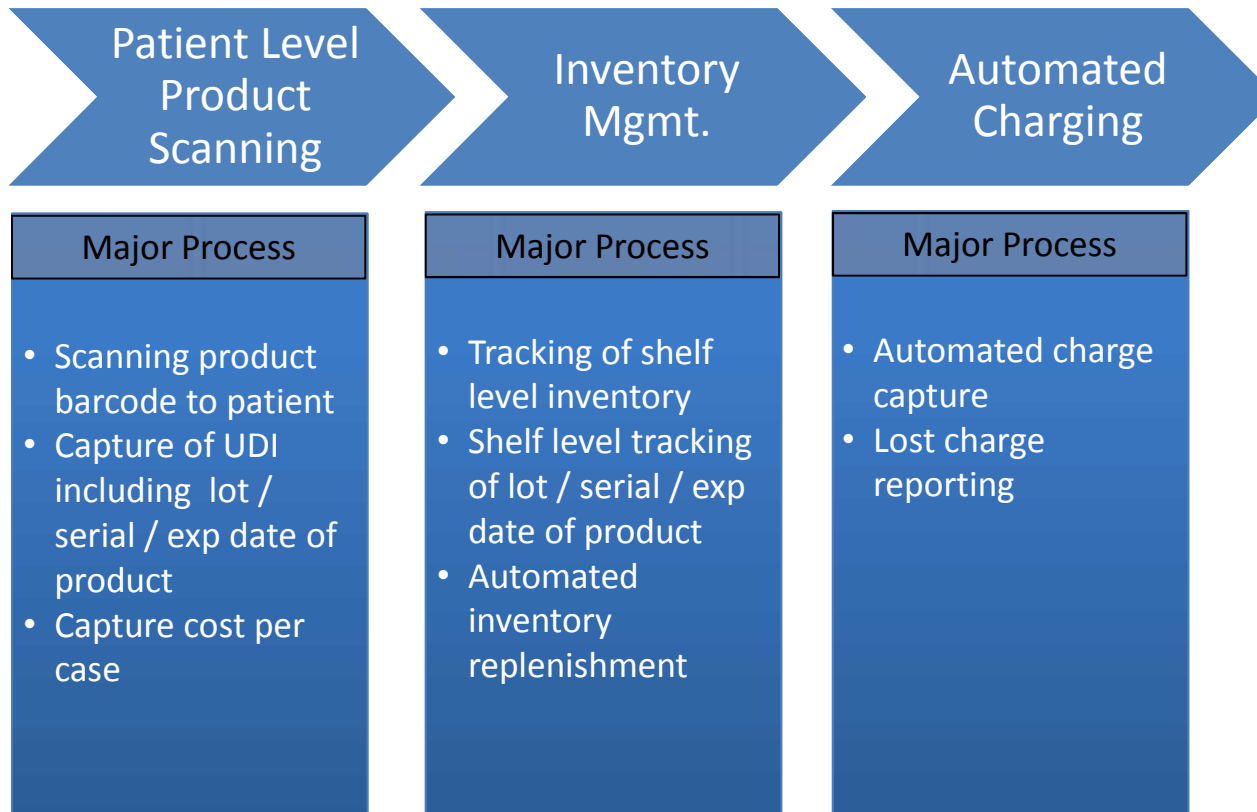
# Performance Solutions - What we did...



## Changes to Cath Lab Process

- The UDI project required us to make changes to how the Cath Lab process works
- The changes we made improved many aspects of the workflow in the Cath Lab

# Performance Solutions - What we did...



Goal: Enable capture of the UDI to the patient... Apply automation to highly manual process



# UDI Issues

- **DI or PI or both?**
- **Barcode scanning and workflow**
- **Software limitations (the double scan)**
- **Not a single standard (GS1 and HIBC)**
- **Multiple barcodes – Which one is UDI?**
- **Link to GUDID**
- **Link to supplemental data (AUDI)**
- **Supply chain partnership**





# Thanks!

*Joseph P. Drozda, Jr., M.D., F.A.C.C.*

*Director, Outcomes Research*

*Mercy*

*14528 South Outer Forty*

*Chesterfield, MO 63017*

*314-628-3864*

*Mobile: 314-308-1732*

*[Joseph.Drozda@Mercy.net](mailto:Joseph.Drozda@Mercy.net)*