

DIGITAL HEALTH APPLICATIONS IN MEDICAL DEVICE POST MARKET SURVEILLANCE

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ESC CARDIOVASCULAR ROUNDTABLE MEETING
TALLINN, ESTONIA
4 OCTOBER 2019

Medtronic
Further, Together

The Saturday
Evening
POST
FOUNDED IN 1774 BY
Benjamin Franklin

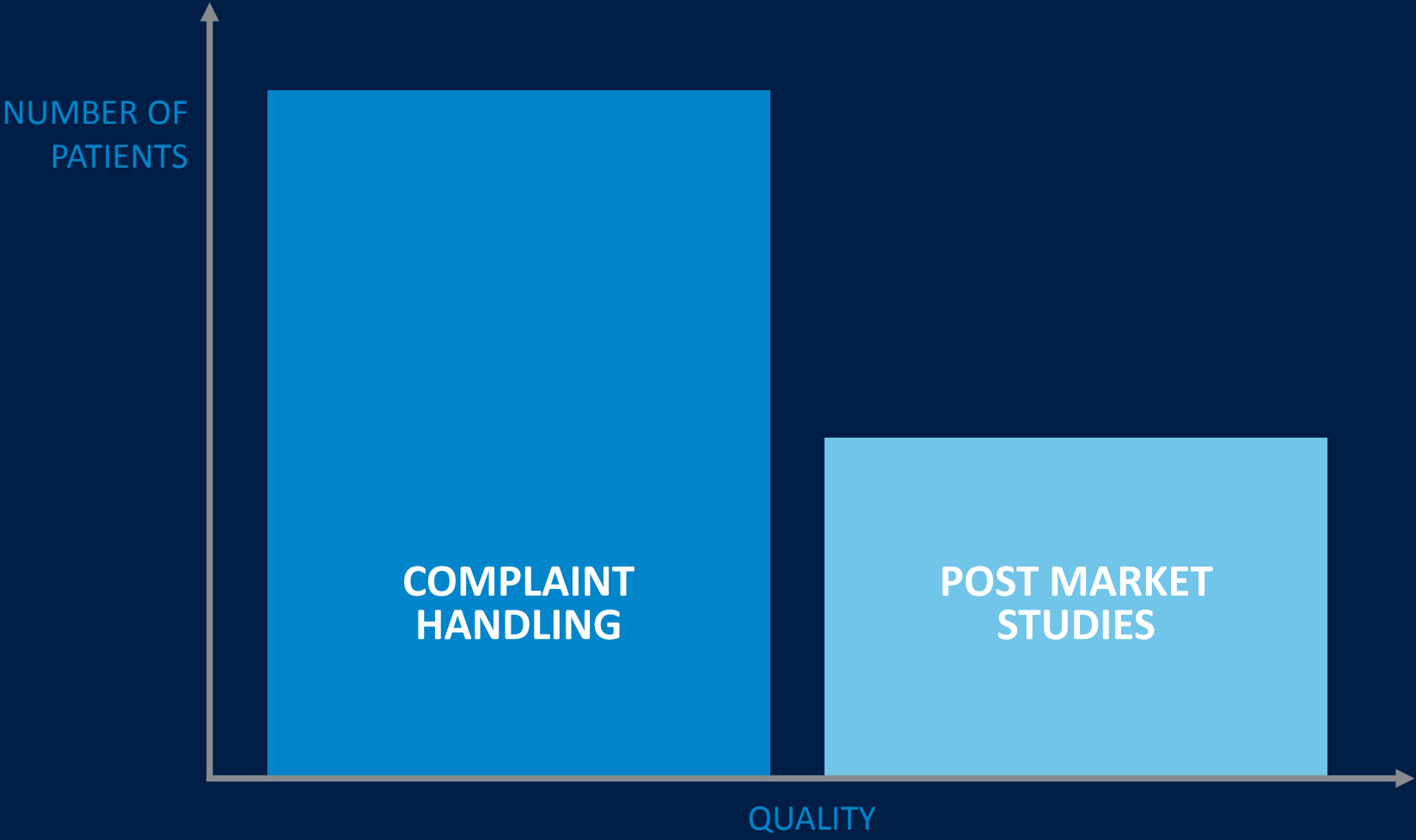


RATIONALE BEHIND POST-MARKET SURVEILLANCE

**To determine if
post-market event
rates align with the
premarket events**

**To capture
unanticipated events
not previously known
or understood**

TRADITIONAL CLINICAL DATA SOURCES



PROS AND CONS

	Complaint Data	PSR/PMCF
Population Size	+++	+
Quality	+	+++
Event Rate Monitoring		+
Data Reporting Lag	Variable	Per study protocol
Data Missingness	High	Medium

LIMITATIONS TO IMPROVE SURVEILLANCE ON EXISTING PLATFORMS

- Enrollment cadence
- Development of next generation devices before understanding lessons from current generation
- People move roughly 11–12 times in a lifetime
- Costly and burdensome to all stakeholders
- Study fatigue with extended follow up



1.8M
PATIENTS
ENROLLED

227M
TRANSMISSIONS

17.7K
CLINIC
ACCOUNTS

83
COUNTRIES



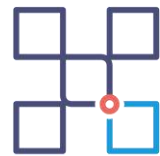
pcornet[®]

The National Patient-Centered
Clinical Research Network

MINICOR

Multi-modal International Cardiovascular Outcomes Registry

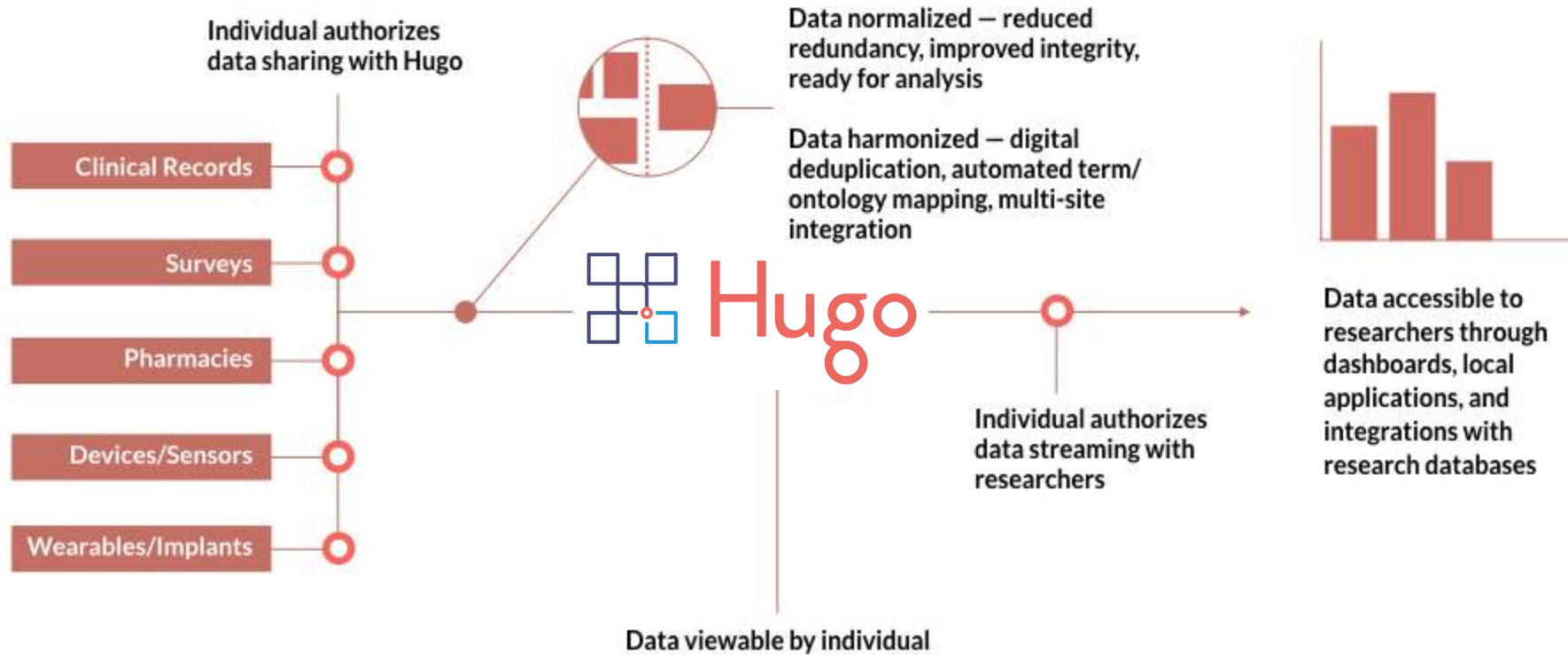
OM1



Hugo

Data Flow:

People Powered / Secure Data Streaming Technology

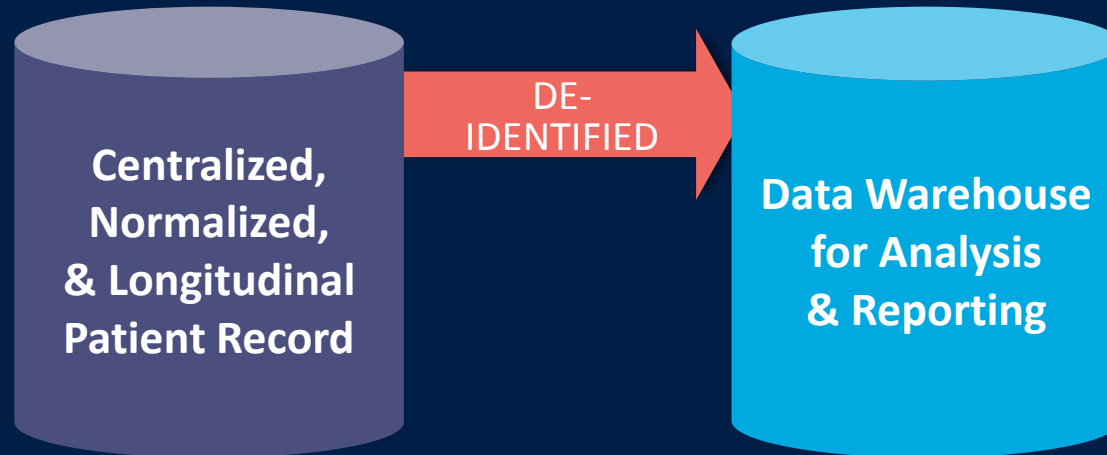


THE HUGO MODEL

GENERATION OF LONGITUDINAL RECORD AND TRANSMISSION TO MEDTRONIC

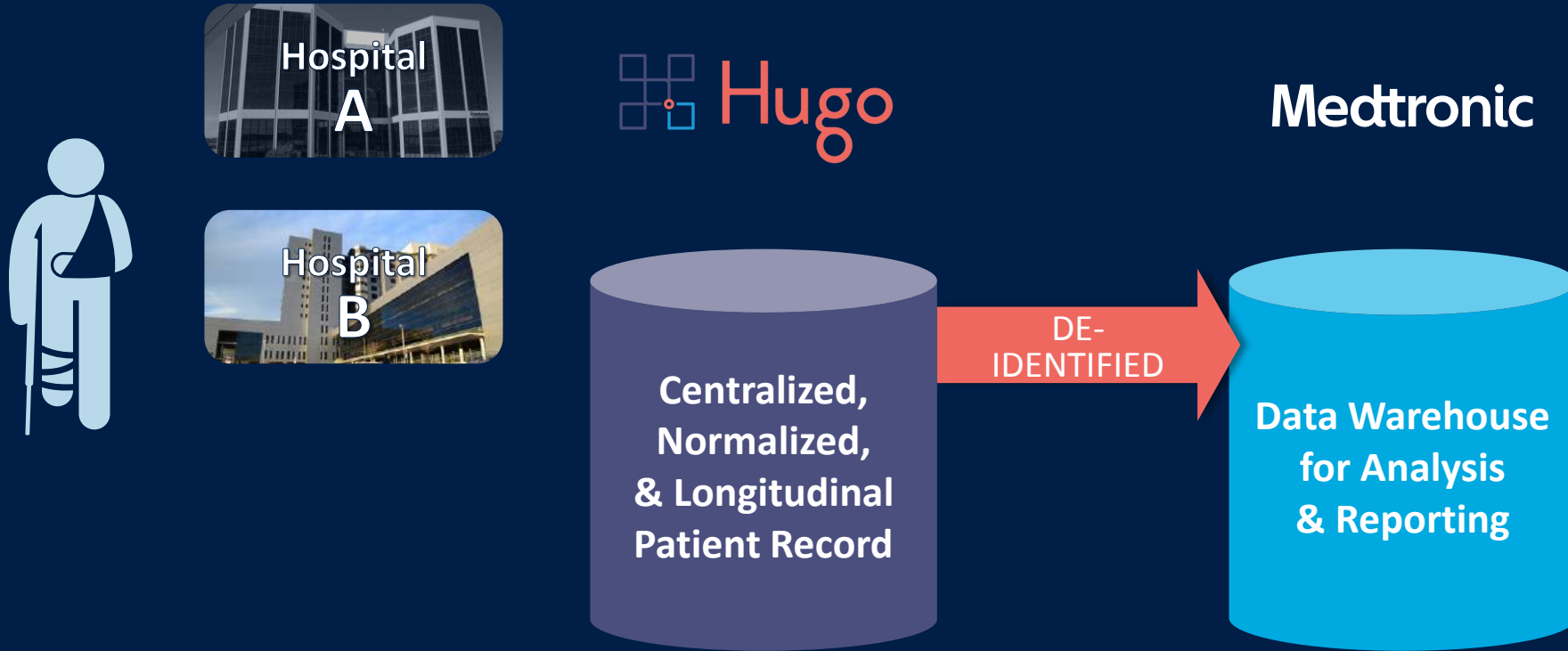


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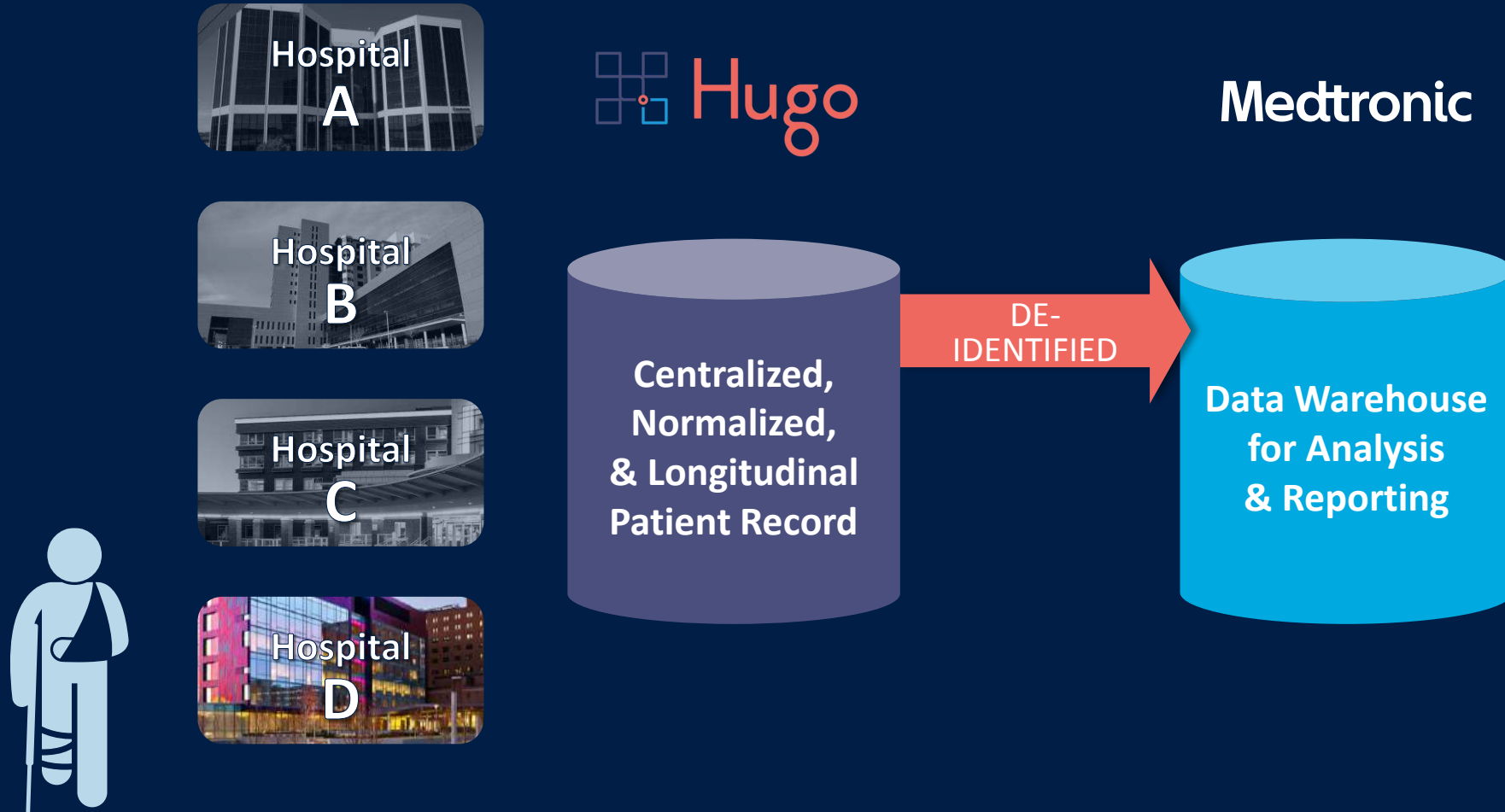
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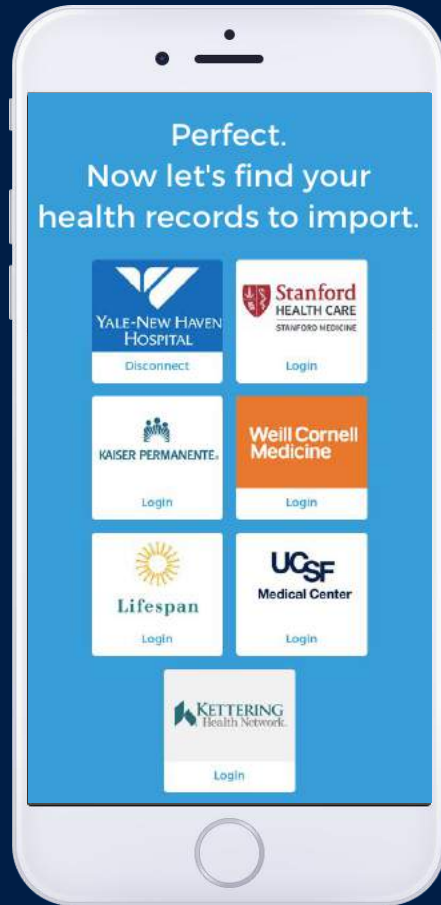
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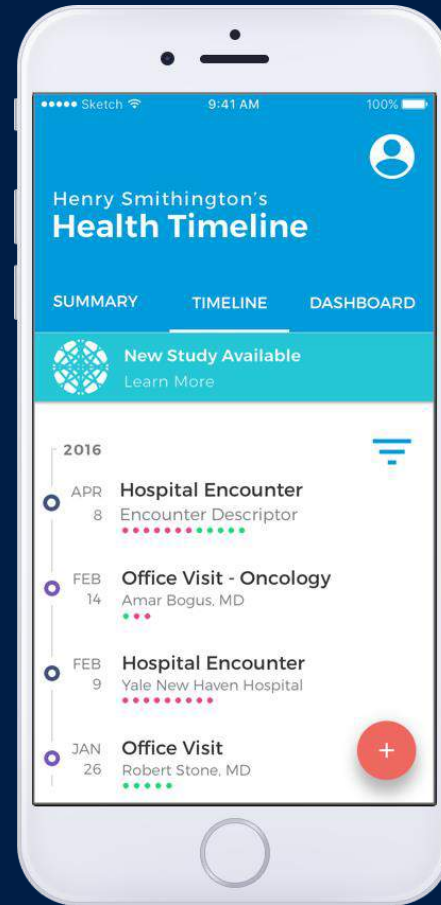


HUGO – A PEOPLE POWERED DATA PARTNERSHIP

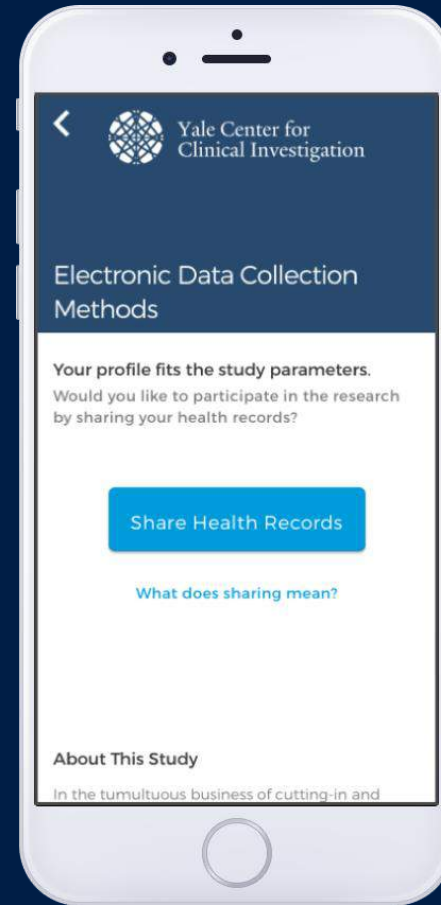
Collect.



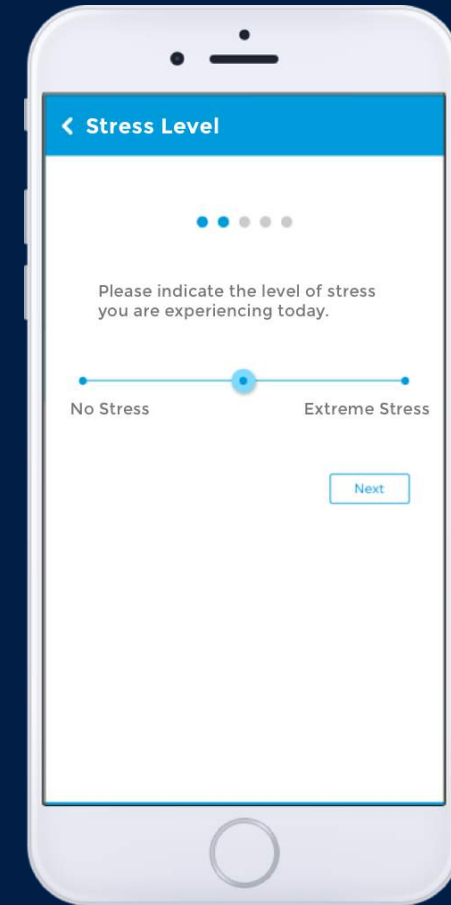
Organize.



Share.

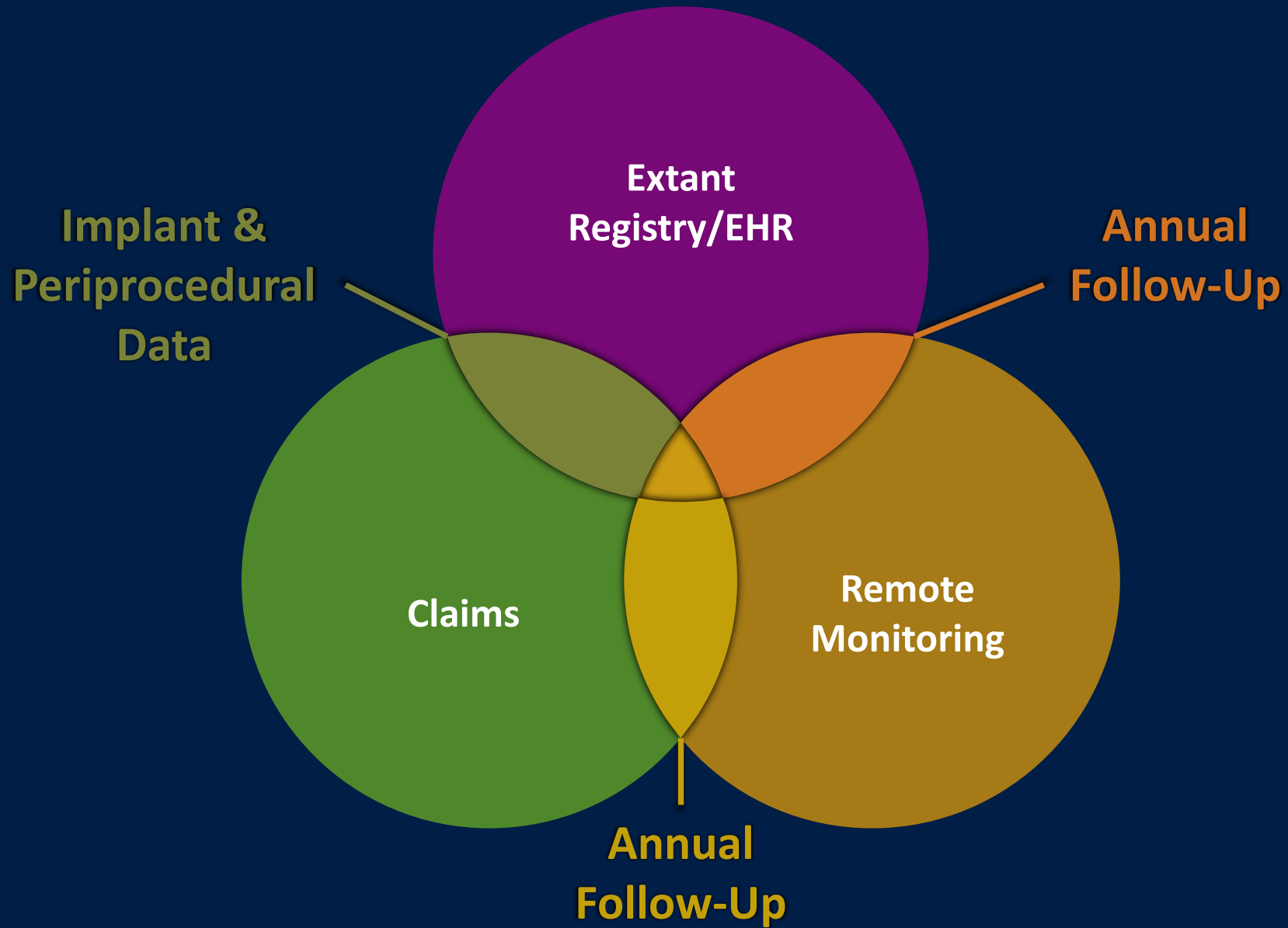


Engage.



MOVING INTO THE FUTURE





**THE
FUTURE IS
HERE,
BUT...**

