DIGITAL HEALTH APPLICATIONS
IN MEDICAL DEVICE
POST MARKET SURVEILLANCE

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ESC CARDIOVASCULAR ROUNDTABLE MEETING
TALLINN, ESTONIA
4 OCTOBER 2019
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

NUMBER OF PATIENTS

QUALITY

COMPLAINT HANDLING

POST MARKET STUDIES
## PROS AND CONS

<table>
<thead>
<tr>
<th></th>
<th>Complaint Data</th>
<th>PSR/PMCF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population Size</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Quality</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Event Rate Monitoring</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Data Reporting Lag</td>
<td>Variable</td>
<td>Per study protocol</td>
</tr>
<tr>
<td>Data Missingness</td>
<td>High</td>
<td>Medium</td>
</tr>
</tbody>
</table>
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
Data Flow:
People Powered / Secure Data Streaming Technology

Individual authorizes data sharing with Hugo

Data normalized — reduced redundancy, improved integrity, ready for analysis
Data harmonized — digital deduplication, automated term/ontology mapping, multi-site integration

Data accessible to researchers through dashboards, local applications, and integrations with research databases

Individual authorizes data streaming with researchers

Data viewable by individual

Clinical Records
Surveys
Pharmacies
Devices/Sensors
Wearables/Implants

Hugo
THE HUGO MODEL
GENERATION OF LONGITUDINAL RECORD AND TRANSMISSION TO MEDTRONIC

Centralized, Normalized, & Longitudinal Patient Record

DE-IDENTIFIED

Data Warehouse for Analysis & Reporting
THE HUGO MODEL
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Hospital A

Hospital B

Hospital C
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Hospital A

Hospital B

Hospital C

Hospital D
HUGO – A PEOPLE POWERED DATA PARTNERSHIP

Collect.

Organize.

Share.

Engage.

Perfect. Now let's find your health records to import.

Henry Smithington’s Health Timeline

Electronic Data Collection Methods

Your profile fits the study parameters. Would you like to participate in the research by sharing your health records?

Share Health Records

Stress Level

Please indicate the level of stress you are experiencing today.

No Stress

Extreme Stress

[Images of mobile app screens showing different features and interactions]
MOVING INTO THE FUTURE

The NEST Ecosystem

- Clinician Groups
- Industry
- Payers
- Patient Groups
- Regulators
- Health Systems
EP PASSION

Implant & Periprocedural Data

Extant Registry/EHR

Annual Follow-Up

Claims

Remote Monitoring

Annual Follow-Up
THE FUTURE IS HERE,

BUT...