THE NATIONAL BREAST IMPLANT REGISTRY

Pathway to Generation of Relevant Evidence

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The Story of the National Breast Implant Registry
SILICONE IMPLANTS

Banned in 1992
PIP breast implant scandal may involve 7,000 more British women
Tests show that substandard silicone was used to fill the implants for much longer than had been thought

Sarah Boseley, health editor
The Guardian, Thursday 15 March 2012 13.55 EDT

About 7,000 more women in the UK have received potentially faulty PIP breast implants than previously thought, the government said today. Photograph: Andrew Milligan/PA
FDA Reports Link Between Breast Implants and a Rare Cancer
Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology
The Opportunity: Stakeholder Collaboration

FDA

ASPS/PSF

Device Manufacturers

Patients

Women’s healthcare providers
National Breast Implant Registry Goals

• Optimize safety

• Facilitate the safe and efficient entry of new device technology in the US market

• Provide a framework for more in-depth studies
What will the Registry provide to Stakeholders?

- Benchmarking reports for surgeons to compare to national averages
- Support for innovation in breast implant device design
- An efficient mechanism to study unanswered research questions
How will it work?

<table>
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<tr>
<th>Level 1 NBIR Data Collection</th>
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<tr>
<td>Implant</td>
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<tr>
<td>Reoperation</td>
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How will it work?

Data Uploads from Existing Device Tracking Infrastructures

Data Entry from ASPS Member Surgeons

Level 1 NBIR Data Collection

- Implant
- Reoperation

Patient-reported Outcomes data
NBIR Progress to Date

- Systematic Review of Breast Implant Literature
- Stakeholders Charter
- Data Collection Strategy and Case Report Form
- Data Flow Charts and Protocol
- Database Vendor selection
- Governance Model
NBIR Next Steps

• Further refinement of governance structure
• Establish consensus on business model
• Selection of governing and operating committees
• Database development with data collection beginning in late 2015/early 2016
Summary: NBIR Priorities

1. Ensure patient safety through enhanced long-term device surveillance

2. Obtain high quality, clinically meaningful evidence to improve outcomes

1. Facilitate the safe and efficient entry of new device technology into the US market