

# 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

# FDA

Banned  
in **1992**

abc NEWS  
.com

## 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

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**Sarah Boseley**, health editor

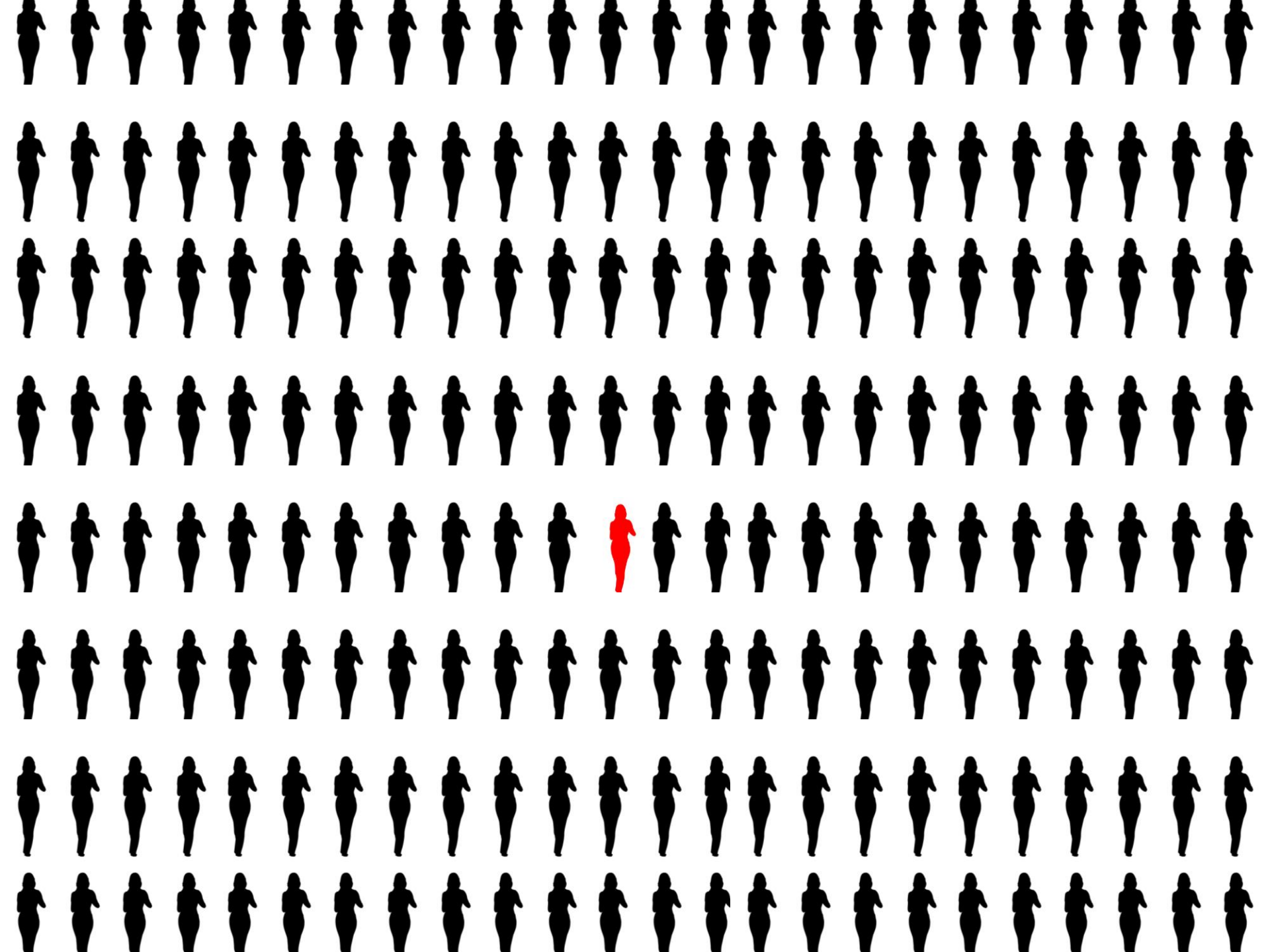
The Guardian, Thursday 15 March 2012 13.55 EDT



About 7,000 more women in the UK have received potentially faulty PIP breast implants than previously thought, the government said today. Photograph: Andrew

## FDA Reports Link Between Breast Implants and a Rare Cancer







Patient

Registry and

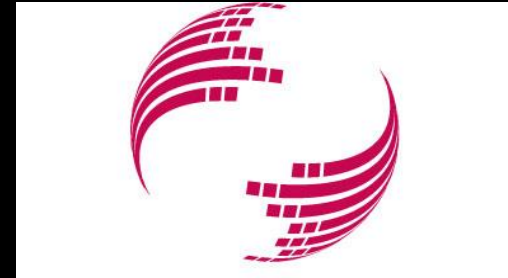
Otcomes

For Breast

Implants and Anaplastic Large Cell

Lymphoma

Etiology and Epidemiology



# PROFILE



# The Opportunity: Stakeholder Collaboration

FDA

ASPS/PSF



Patients

Women's  
healthcare  
providers

Device Manufacturers

# 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?

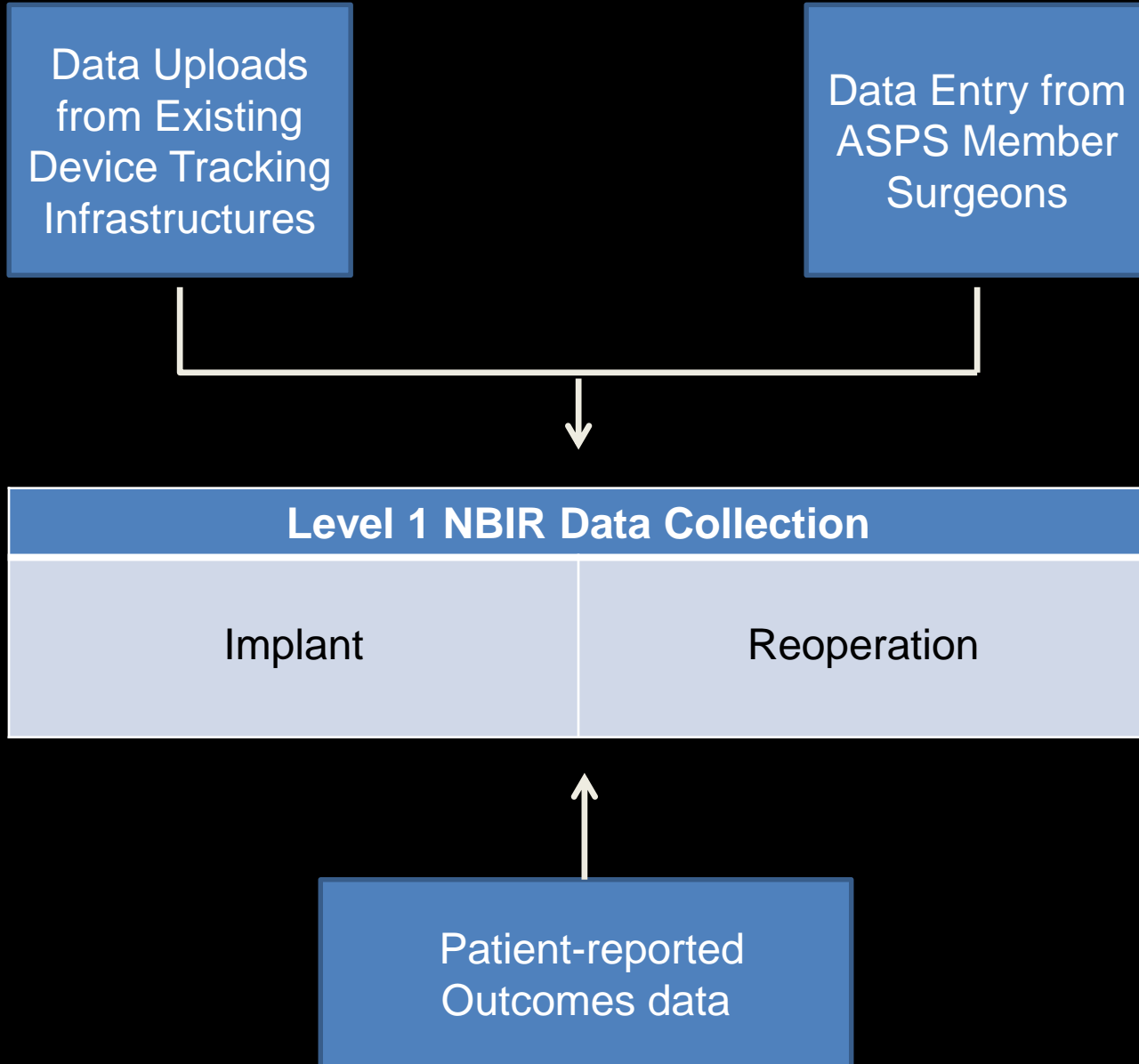
- Benchmarking reports for surgeons to compare to national averages
- Support for innovation in breast implant device design
- An efficient mechanism to study unanswered research questions



# How will it work?

Level 1 NBIR Data Collection	
Implant	Reoperation

# How will it work?



# 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



Thank you

