

The Total Product Life Cycle:
**A Focus on Postmarket Surveillance
and Vigilance**

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The Postmarket Period

What do we hope to accomplish?

- ✍ Identify low frequency events
 - those not detected in premarket
 - confirm ambiguous signals from premarket
- A Global opportunity:
 - 📖 The vigilance report exchange program
 - 📖 Harmonized reporting rules and forms

The Postmarket Period

What do we hope to accomplish?

- ✍ Detect changes (usually problems) in clinical risk from manufacturing or other changes that were not evaluated clinically.
- E.g., changing the firing method for ceramic-composite hip implants resulted in early product failures

The Postmarket Period

What do we hope to accomplish?

- ✍ Identify events or performance that takes longer follow-up than in the premarket period.
 - E.g., Pacer lead life


The Postmarket Period

What do we hope to accomplish?


- ✍ Identify problems that occur in “real world” use associated with:
 - Learning curve / training
 - Human factors
 - Off Label Use
 - Vulnerable populations

The Postmarket Period


What do we hope to accomplish?

 Identify problems as new technology interacts with the device:

- E.g., :





-  Medical Telemetry and Digital TV broadcasts

-  Pacemakers Theft Detection Devices

-  Wheel Chairs and Cell Phones

Postmarket Tools

Clinical Trials

-  Follow-up of premarket clinical trial participants
-  New Post Approval Trials
-  Trials on the next generation of the product
-  Trials to expand indications
 - New use
 - New population

Postmarket Tools

Spontaneous Adverse Event Reports



Strengths:

- unusual,
- Unexpected, and
- severe events



Limitations:

- Incomplete reporting
- Variable reporting
- Summary reporting is adequate for a large proportion of the reports
- Not well suited for IVD's and products unlikely to directly cause significant morbidity

Postmarket Tools

Surveillance Networks (MeDSUN)



Strengths:

- More complete reporting
- Numerators and Denominators
- Better able to characterize Use Errors
- Program is likely to help facilities reduce errors



Limitations:

- Only can detect relative high incident events
- Local benefits limited to participating hospitals



Pay Off:

- May eliminate the need for some types of MDR reports for common events – nationwide
- May be a useful risk management tool for local facilities

Postmarket Tools

Epidemiology



Case-Control Studies

- Usually require more data than is routinely collected



Registries

- May not be that much larger in size than premarket studies
- Some products need a control group to assess findings




Tracking Requirements


- In the US law – a notification, not a surveillance tool

Manufacturer's Postmarket Tools


CAPA Systems

 A good CAPA system is key to the manufacturer's credibility as a problem solver

Recalls

 An underutilized opportunity to solve cross-cutting problems

Product Launch Training Findings


 A Human Factors opportunity

The Postmarket Period


Special Problems

 Abandoned models

- E.g., Y2K orphans

 “use at your own risk”

 Refurbished

 Reused single use devices

PostMarket: A Global Perspective

Key Common Elements



Clinical Trials of

- adequate quality, and
- with significant follow-up
- useful in assessing risk/benefit

around the world



CAPA Systems

- Sensitive problem detection
- Credible problem solving



Vigilance Systems

- World wide
- Transparent
- Tailored to time increasing role of the Consumer

PostMarket: A Global Perspective

Key Common Elements



Post Market Tool Kit

- Epidemiology and Surveillance networks to rapidly resolve early warnings



Trust

- Transparency
- Communication
- Joint efforts