



Managing Device Safety in the 21st Century

What is the role/Responsibility of Industry?

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Headlines!

***All medical devices will fail at some point in time.....
It just depends on whether it is expected or not!***

***All medical devices save and positively impact lives...
...but they also have the potential to cause harm!***

***Medical devices are extremely reliable.....perhaps
some of the most reliable items people will come in to
contact with!***

To answer the question!

- **What is the philosophy of the EEA Regulation**
- **What is industry mandated to do?**
- **What is 'good' for industry to do?**
- **Moving forward!**

Clarification!

“Medical Device” here encompasses:-

- **Active implantable Medical Device (AIMD)**
- **Medical Device (MD)**
- **In-Vitro Diagnostic Device (IVD)**

Philosophy of EEA Regulation

- **Has a common platform across EEA**
 - Reduce trade barriers
- **Safety is primary goal**
 - Patient, users (others)
- **Proportional to the risk of the device**
 - The intended therapy/use
 - Location in/on/near body/tissues
 - Risks of using/getting the device to its site of therapy
- **Wide clinical use may reveal emergent issues**
 - Post-production safety & performance monitoring
- **Benefits of therapy out-weigh the risks**

Proportional to Risk

- **Classification of devices in to “Classes” based on risk**
 - AIMD, MD Class III & IVD Class D – highest risk
 - MD Class I and IVD Class A – lowest risk
- **Requirements to prove safety are higher for higher risk device groups**
 - “Essential Requirements” are greater
- **Higher the risk the more third party scrutiny of proof**
 - Third party = Notified Body

Explanations

- **Notified Bodies – designated/licensed by National Competent Authority (NCA)**
- **NCA = Regulator of Medical Device Industry in each EEA member state**
- **Standards (ISO / EN) can be important**

Manufacturer Responsibility



“Cradle to Grave”



Manufacturer Responsibility

RISK MANAGEMENT

Pre-Market

Essential Requirements

design, materials,
components,
manufacturing, etc

Pre-CE Mark Clinical Study

Essential Requirements

Post-Market Phase

Essential Requirements

Monitor safety & performance
Quality Assurance
Corrective action if necessary

Manufacturer Responsibility

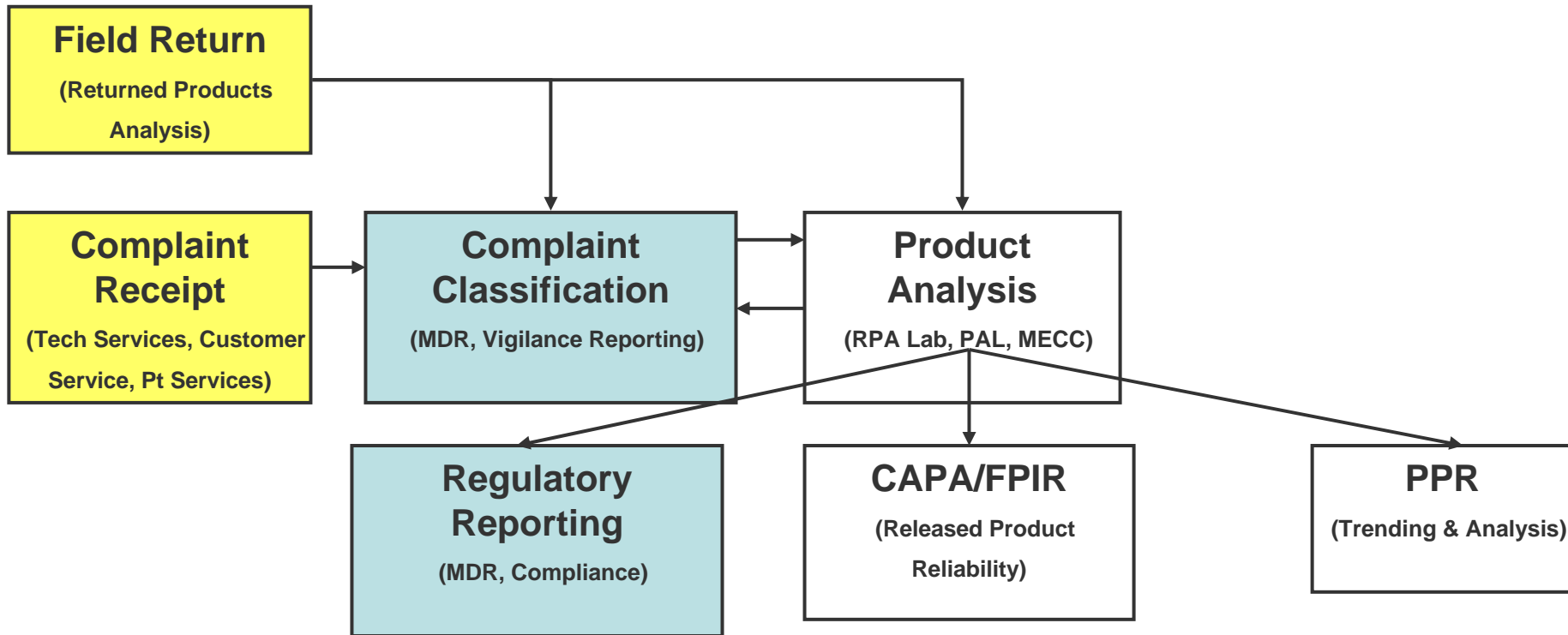
Pre-Market & Clinical Essential Requirements met –
CE Mark can be applied

Post-Market Phase

- **Wider clinical use - emergent safety issues?**
- **“QA” issues may arise**

- **Must establish & maintain a systematic process for gathering device experience in the post production phase....ie safety & performance info. about medical devices in the market place.**

Manufacturer Responsibility



Manufacturer Responsibility

Post Market Surveillance (PMS)

- **Can be active**
 - Product Performance Study
 - PM clinical Study
 - User questionnaires/acceptance studies
 - QA activities
- **Can be passive**
 - Collect product complaints / adverse incidents
 - Publications
- **Aim is to reveal emergent & “QA” safety issues**

Manufacturer Responsibility

- **PMS activities feeds Vigilance activities**
- **Vigilance Reporting informs NCA's of actual or potential device safety issues**
- **Investigation by manufacturer with NCA oversight**
- **MAY require Field Safety Corrective Action (FSCA)**
 - **Field Safety Notice (FSN) circulated to clinicians**
- **Planning & execution by manufacturer**
- **Oversight by NCA's**
 - **May decide to reinforce or amend FSN via own communication (MDA)**
- **Many NCA's publish all FSN**

Comments

- **FSCA's are Risk based**
- **Increased sensitivity to safety issues**
- **Demand for greater transparency**
- **More FSNs circulated**

Challenges

- **High risk and recommendations made**
 - **Clinician advice**
- **Common FSN to different markets**
- **Risk of corrective intervention can be greater than risk of no intervention**
- **Clinician choice in management of patients**

'Good' things to do!

- **Innovation –**
 - Unmet clinical needs
 - New technologies, therapies, procedures
- **Reduce trauma**
- **Simplify procedures**
- **User-friendly interfaces**
- **'Smart' devices**
- **“Inter-device” safety**
- **Partner with clinicians**

'Good' things to do!

Technical support, Education and Training

- Improve safety
- Impact clinical outcomes
- *Industry not mandated to provide*
 - *But it makes sense to use it!*

Moving Forward

- **Medical Devices Directives have been revised!**
 - Although no changes to IVDD
- **Full application in Law 21st March 2010**
- **Clarification of ‘grey areas’**
- **Increased scrutiny by NB’s**
- **Overall effect will improve safety of MD’s**
- **Logical evolution of proportional risk base system**

Moving Forward

Device capabilities can improve management of safety

- **Device integrity monitors / alarms**
- **Home / remote monitoring**
 - Not just follow-up efficiencies
- **Devices currently without monitoring functions**
- **?Integrity monitors?**

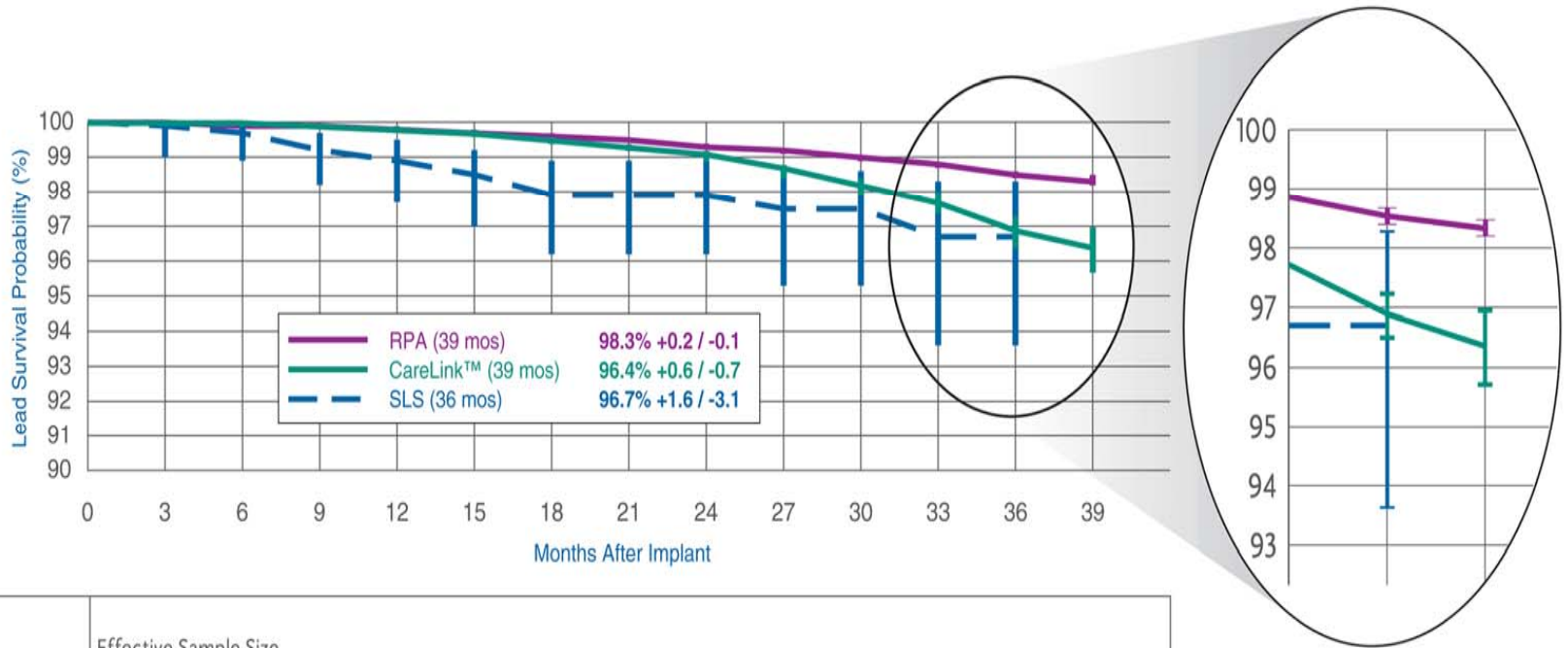
- **There is a cost to safety!**

Moving Forward

PMS Clinical Studies

- **Regulations place more weight on these**
 - Especially high risk devices
- **Pre-CE mark clinical studies continuing /expanding in post-market phase**
- **More Product Performance data should be available**
 - Demonstrate product survival

Example – Product Performance



Model 6949	Effective Sample Size													
	0 mo	0-3 mo	3-6 mo	6-9 mo	9-12 mo	12-15 mo	15-18 mo	18-21 mo	21-24 mo	24-27 mo	27-30 mo	30-33 mo	33-36 mo	36-39 mo
RPA	185,526	182,172	174,280	162,545	146,952	130,313	113,684	97,181	81,004	65,116	49,673	34,989	21,980	11,256
CareLink™	21,500	21,442	21,248	20,878	20,307	19,287	17,721	15,656	13,209	10,148	6,798	4,132	2,254	951
SLS	735	724	693	636	552	463	375	304	252	206	164	123	80	41

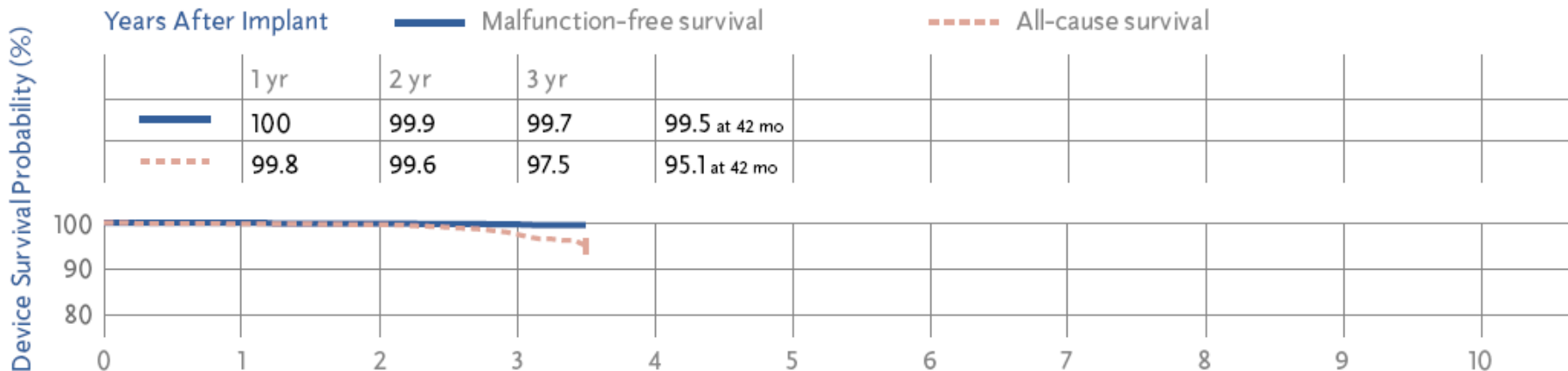
Survival Curve for Fidelis 6949 as of May 7, 2008

Example – Product Performance

7274 Marquis DR

Product Characteristics

US Market Release	Mar-02	NBD Code	VVED
Registered US Implants	48,000	Serial Number Prefix/Xray ID	PKC
Estimated Active US Implants	29,000	Max Delivered Energy	30 J
Normal Battery Depletions	111	Longevity	See page 32
Malfunctions	64 (9 related to advisory)		
Therapy Function Not Compromised	32 (1 related to advisory)		
Therapy Function Compromised	32 (8 related to advisory)		
Advisories	1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short		



Threats!

Recasting of the Medical Devices Directives

- **Announced just after revision**
- **Claimed concerns over safety, especially of high risk devices**
- **Industry opposes this 'Recasting' in the suggested form**
- **Some NCA's also oppose (MHRA)**
- **Clinician community needs to engage with recasting process**

Summary

- **Industry has central responsibility/role**
 - “Cradle to Grave”
- **Industry is necessarily Regulated**
- **Regulations revised to improve safety**
- **Partnership of Industry, Clinicians and Regulators**
 - Monitor safety
 - Improve safety
 - Innovation

Thank You!