Industry Challenges with Software as a Medical Device

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Presentation objectives

- Describe the top four industry challenges with Software as a Medical Device (SaMD)
- Explore sample approach for assessing software;
- Highlight impact of Medical Device Regulation on software;
- Discuss FDA regulation of Clinical Decision Support software;
- Discuss key software provisions of recent US legislation;
- Plea for global harmonization!
Multiple Challenges:

- What is an SMD in each country?
- Development costs and timelines;
- Change control across countries and over time;
- MDR implementation,
- FDA’s Digital Health Innovation.
Deciding What’s a Device

- **Software is becoming increasingly popular with the pharmaceutical business**
  - Including with Research Units for use in Clinical Studies
  - Extension of patient labeling
  - Patient adherence

- **Frequently originates in one country, then expands**

- **Differing laws in each country complicate development plans and increases time/cost**

- **The compliance processes must be followed from the start of a SaMD project—need the designation early**
Pfizer SaMD Assessment
2014 through 2017 YTD

2014: 40 Assessments Submitted
2015: 50 Assessments Submitted
2016: 100+ Assessments Submitted
2017: on track for 100+

Under Evaluation    Under Development    Deployed, significant expansion in progress
Development Costs and Timelines

• **Perception:**
  - Software development is cheap and fast
  - Medical Device quality systems are not

SaMD is estimated 2-3X cost and time

*Therefore*: Avoid SaMD designation
SaMD – Sample Project Team Composition

- Sponsoring Organization Team Lead (project owner)
- Medical
- PGS Quality Ops*
- BT*
- GCMC
- Legal (Brand/Country, Privacy, Reg Law)
- Safety
- Key business/research colleagues
- Regulatory Strategy
- Project manager (from Sponsoring Org.)
- Medical Quality Assurance
- Others (as needed)
- Regulatory Ops
SaMD Change Control

After initial Medical Device approval, design changes

- Software bugs and tweaks
- Customization for countries
- Translation requirements
- Individualization by Country

Keeping track of what’s out there.
EU Medical Device Regulation Implementation

Rule 11

- Software intended to provide information which is used to make decisions with diagnosis or therapeutic purposes is classified as class IIa...

- Software intended to monitor physiological processes is classified as class IIa...

- Clinical Evaluation

- Technical Files
FDA’s Digital Health Innovation

• 21st Century Cures Act exempts Clinical Decision Support Software
• Exemption vs Enforcement Discretion
• Pre-certification Pilot-companies with proven quality system implementation for SaMD life cycle
• 9 companies initially for pilot. Many applications
• Potentially bypass FDA review
Objectives: Recap

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Global Harmonization, Please!