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mHealth and the Medical Device Framework – A Closer Look

MovingLife project's Stakeholder Conference
18 April 2013

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- **New challenges for regulation…**

New challenges for regulation…

- Standalone Sofware might be medical device
- Communication System (wireless data transmission)
- Complex systems (that combine medical devices, softwares, software as medical devices)

- **Stand alone Software qualification**

Software qualification

Sofware is qualified as a medical device when specifically intended by the manufacturer to be used for one or more of medical purposes set out in the definition of medical devices.

Recital 6, Diretive 2007/47/EC (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:EN:PDF)
MEDDEV 2.1/6 (http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf)

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Medical Device Definition

… any instrument, apparatus, appliance, **software,** material or other article, **whether used alone or in combination,** including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,

intended by the manufacturer to be used for human beings for the purpose:

- Diagnosis,
- Prevention
- Monitoring,
- Treatment
- Alleviation of disease, injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process…

Diretive 2007/47/EC

Other definitions that might apply…

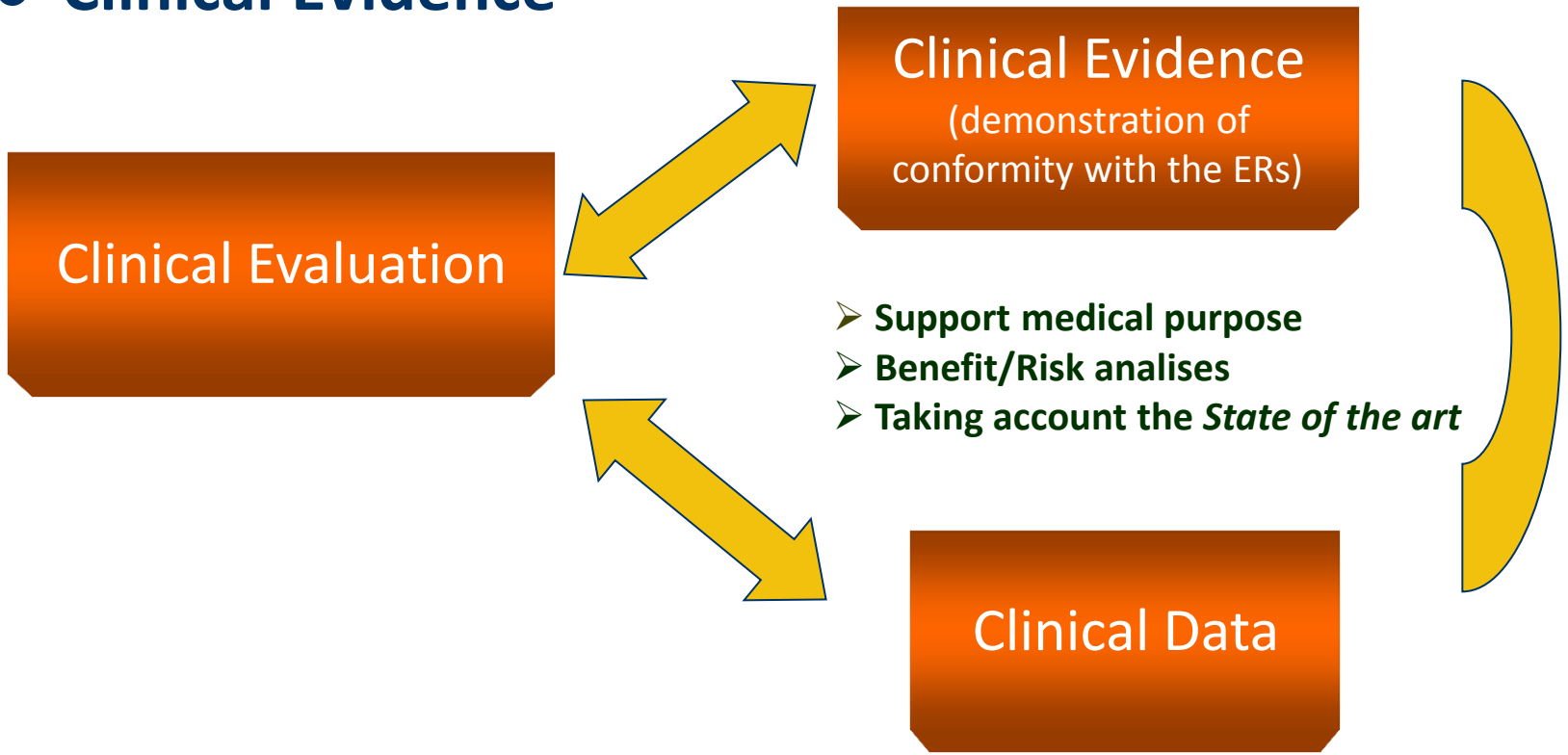
- Acessory (point 2b, article 1of MDD)
- In vitro medical device (point 2c, article 1of MDD)
- Active implantable medical device (point 2c, article 1 of AIMDD)

MDD – Directive 93/42/EEC, as amended (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF)
AIMDD - Directive 90/385/EEC, as amended (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:EN:PDF)
IVDD – Directive 98/79/EC (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:EN:PDF)

Demonstration of conformity and clinical evidence

"Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X."

- **Clinical Evidence**



Annex X, of MDD

MEDDEV.2.7/1 Rev.3 (http://ec.europa.eu/health/medical-devices/files/meddev/2_7_1_ol_en.pdf)

Clinical evaluation

Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based:

- on **risk management** output and under consideration of the specifics of the device/body interaction,
- the **clinical performances** intended
- and the **claims** of the manufacturer

Annex X, point 1.1d) of MDD

Improvements on Medical Device framework*

- **Interoperability/Compatibility**

Point 11.5 of Annex I - Interaction of devices with their environment:

"*Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such as way that the interoperability is reliable and safe*

Point 6.2 (e) of Annex II - Additional information in specific cases

"*If the device is to be connected to other device(s) in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.*"

Annex I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
Annex II - TECHNICAL DOCUMENTATION
* **Revision of the MDDs – COM Proposal (**http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf)

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Point 19.3 m) of Annex I – Information in the instructions for use

The instructions for use shall contain the following particulars:…

For devices intended for use together with other devices and/or general purpose equipment:

- *information to identify such devices or equipment, in order to obtain a safe combination, and/or*
- *information on any known restrictions to combinations of devices and equipment.*

- **Safety/Security**

Point II.11.2 of Annex I - Interaction of devices with their environment:
Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible and appropriate:

…

***(c)** risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or **radio signal interferences**;*

…

***(e)** The risk associated with the possible negative interaction between software and the environment within which it operates and interacts;…*

Annex I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
Annex II - TECHNICAL DOCUMENTATION

- **Standalone Software**

Point 14 of Annex I - Software incorporated in devices and standalone software

Annex I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
Annex II - TECHNICAL DOCUMENTATION

COM's discussion *fora**

MD Classification & Borderlines EG

- WG Software

WG New & Emerging Technologies – NET

- Telemedicine SIG

*http://ec.europa.eu/health/medical-devices/dialogue-parties/working-groups/index_en.htm

Thank you!

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