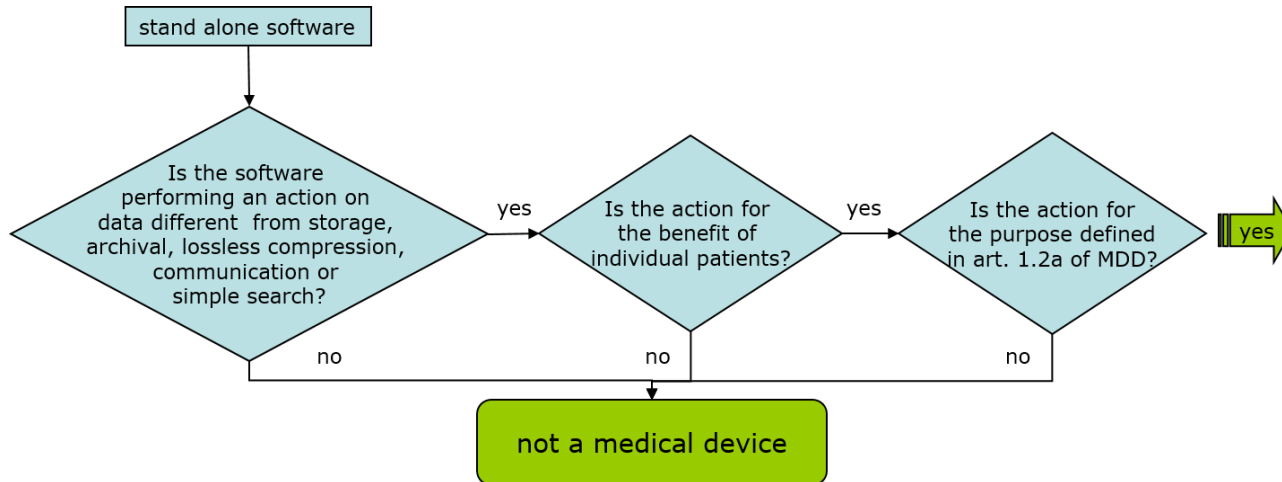# Challenges to clinical decision support

- mental
  - necessity or imperative not recognized (fatalistic attitude towards risk/suffering)
  - factual incomprehension (don't understand it)
  - emotional refusal (don't want it)
  - insufficient endorsement (don't do it)
- clinical
  - too simplistic or insufficient quality (lack of content quality)
  - lack in workflow integration (lack of process quality)
- technical
  - lack in structured patient data
  - insufficient data/semantic interoperability (data and terminology standards)
- financial
  - insufficient funds (often not true!)

$\Rightarrow$ How to overcome these barriers? By clinically useful solutions.

Regulatory affairs I

- stand-alone software
  - **Meddev 2.1/6:** Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices (MDs) (January 2012)

Regulatory affairs II

- MDD 93/42/EEC
  - amended by Directive 2007/47/EG (21 September 2007)

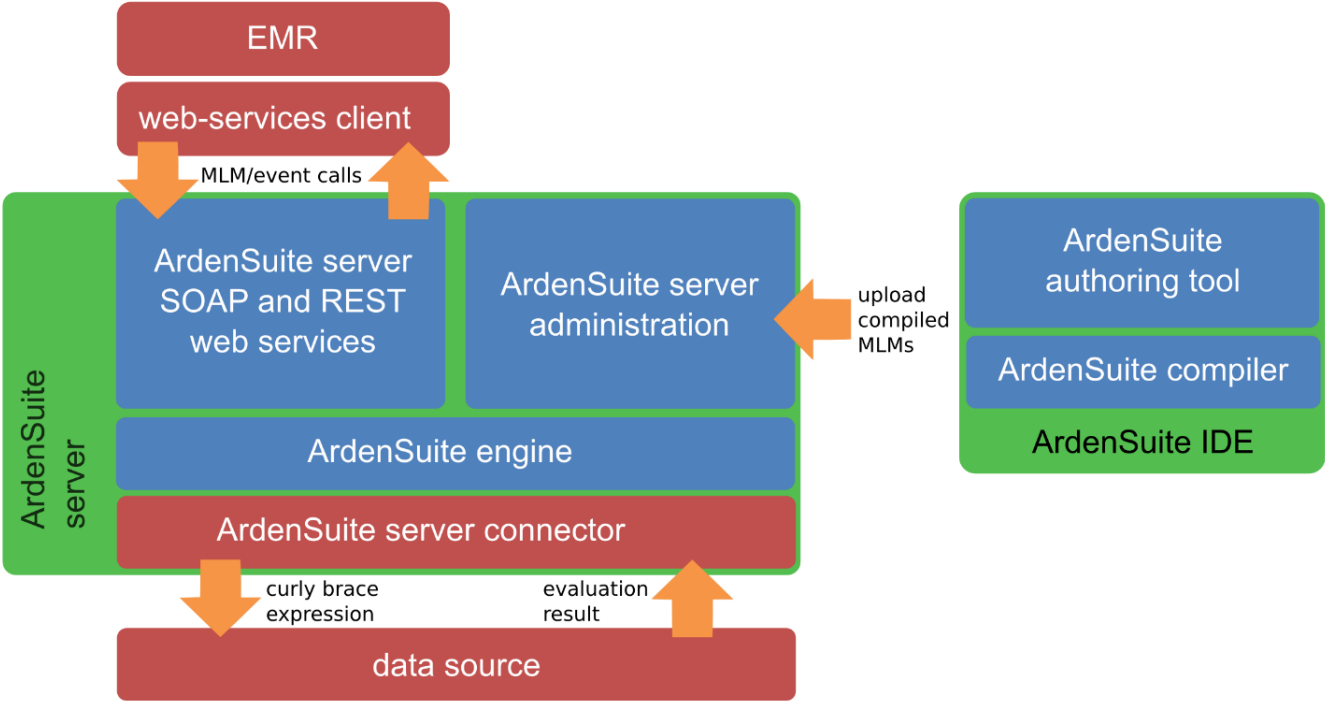Article 1, Paragraph 2a (art. 1.2a of MDD):

Medical device (MD) means any instrument, apparatus, appliance, **software**, material or other article, whether used alone or in combination, ... intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
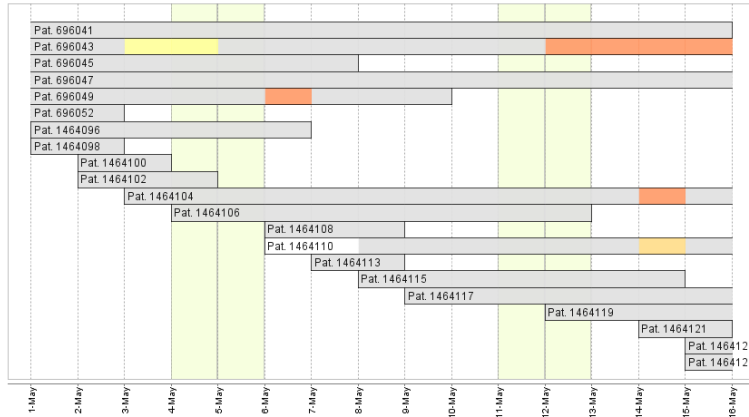- ...

medical device

ARDENSUITE software: generic technology platform for clinical decision support

Moni-ICU:
surveillance of
healthcare-associated
infections

department / patient

Stat. 10865	
Stat. 10896	
Stat. 10897	
Stat. 10898	
Stat. 11051	
Stat. 11053	
Stat. 11082	
Stat. 11083	
Stat. 39690	
Stat. 62354	
Stat. 62621	

Pat.	696343
Pat.	696628
Pat.	1464405
Pat.	1464409
Pat.	1464384
Pat.	696414
Pat.	1464439
Pat.	1464444
Pat.	696434
Pat.	1464393
Pat.	1464380
Pat.	1464470
Pat.	696334
Pat.	1464428
Pat.	1464423
Pat.	696318
Pat.	696328
Pat.	1464402
Pat.	696596
Pat.	696603

1 / 3   [1 - 20 / 43]

Stat. 11408
Stat. 30488

Pat. 1464393

2013-05-29 (Stat. 30488)
2013-05-28 (Stat. 30488)
2013-05-27 (Stat. 30488)
2013-05-26 (Stat. 30488)
2013-05-25 (Stat. 30488)
2013-05-24 (Stat. 30488)
2013-05-23 (Stat. 30488)
2013-05-22 (Stat. 30488)
2013-05-21 (Stat. 30488)
2013-05-20 (Stat. 30488)
2013-05-19 (Stat. 30488)
2013-05-18 (Stat. 30488)
2013-05-17 (Stat. 30488)

BSI-3 (KISS)	100 %DoC
BSI-3 (alert)	100 %DoC
2 clin. signs of sepsis (KISS)	100 %DoC
2 clin. signs of sepsis (alert)	100 %DoC
2 lab. and clin. signs of sepsis (KISS)	100 %DoC
2 lab. and clin. signs of sepsis (alert)	100 %DoC
imp.: no pathogen in specimen other than bloo...	yes
imp.: no blood culture	yes
imp.: not ventilated	yes
imp.: not ventilated (KISS)	yes
imp.: antiinfective	yes

2013-05-16 (Stat. 30488)
2013-05-15 (Stat. 30488)
2013-05-14 (Stat. 30488)
2013-05-13 (Stat. 30488)
2013-05-12 (Stat. 62621, Stat. 30488)
2013-05-11 (Stat. 62621)
2013-05-10 (Stat. 62621)
2013-05-09 (Stat. 62621)
2013-05-08 (Stat. 62621)
2013-05-07 (Stat. 62621)
2013-05-06 (Stat. 62621)
2013-05-05 (Stat. 62621)
2013-05-04 (Stat. 62621)
2013-05-03 (Stat. 62621)
2013-05-02 (Stat. 62621)

BSI-3 (KISS)

AND	100 %DoC
imp.: no blood culture	yes
imp.: no pathogen in specimen other than bloo...	yes
antiinfectives for 5 days	100 %DoC
2 lab. and clin. signs of sepsis (KISS)	100 %DoC

2 lab. and clin. signs of sepsis (KISS)

AT LEAST 2 OF	100 %DoC
pathol. heart rate (definition)	100 %DoC
pathol. Breathing (autom.)	100 %DoC

pathol. Breathing (autom.)

OR	100 %DoC
tachypnea events increasing	100 %DoC
increasing breath rate (80%DoC)	54 %DoC

tachypnea events increasing

tachypnoea event (abs.) (t-1d)	1.46 /h
tachypnoea event (abs.) (Intervall): Max.	3.5 /h

**Moni-NICU:
(surveillance and) alerts for
healthcare-associated
infections**

✓MD

We offer the following ARDENSUITE software licenses:

- Educational license for teaching purposes (ARDENSUITE IDE)

- Research license for research and teaching purposes, (ARDENSUITE IDE, server, and server connector), also as campus license.

- Healthcare license for patient care (ARDENSUITE IDE, server, and server connector/EMR interoperability), also as site or enterprise license for health systems.

- Health IT license for vendor product integration/B2B (ARDENSUITE IDE, server, and server connector/API interoperability), also as annual all-in license.