

## Challenges to clinical decision support

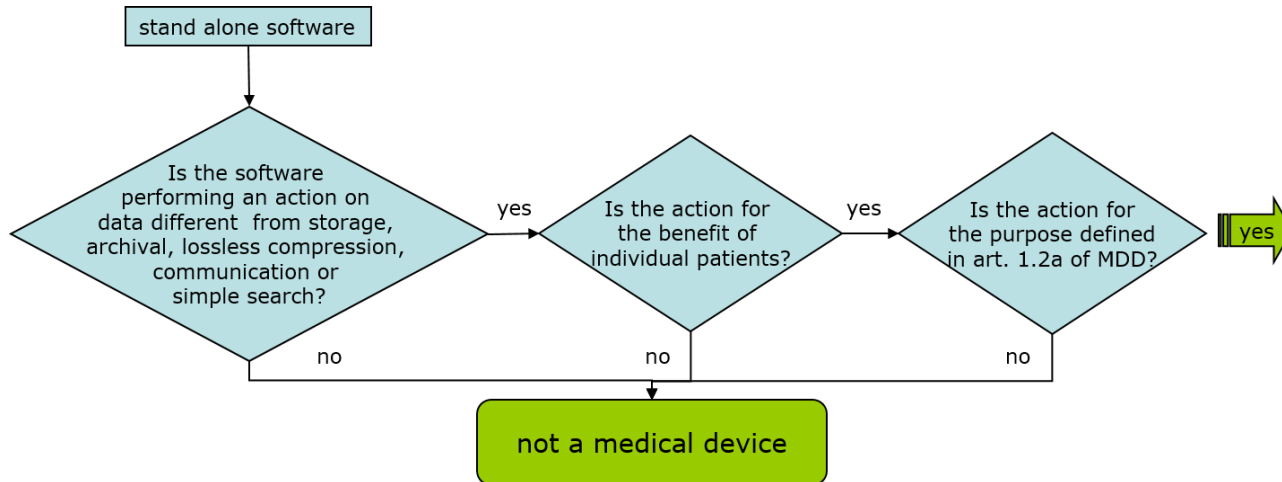
- mental
  - necessity or imperative not recognized (fatalistic attitude towards risk/suffering)
  - factual incomprehension (don't understand it)
  - emotional refusal (don't want it)
  - insufficient endorsement (don't do it)
- clinical
  - too simplistic or insufficient quality (lack of content quality)
  - 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!)

⇒ How to overcome these barriers? By **clinically useful solutions**.

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## 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):

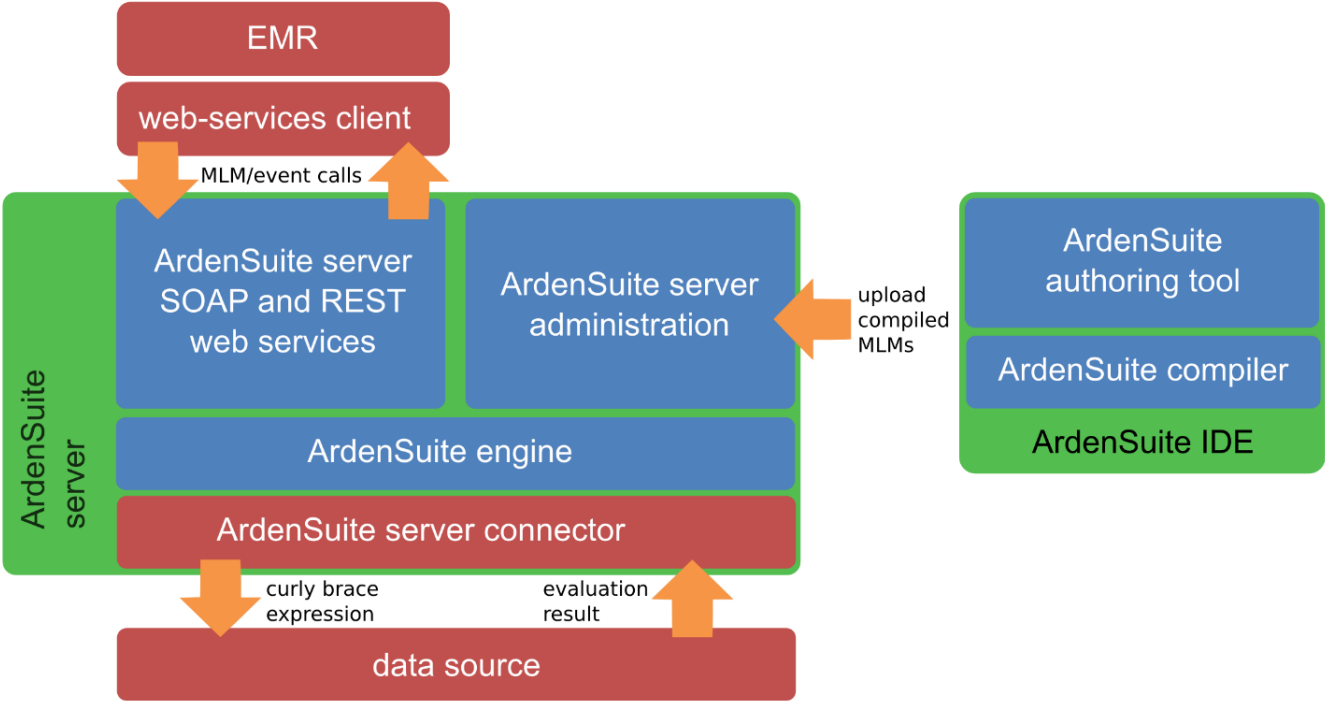
Medical device (MD) means any instrument, apparatus, appliance, **software**, material or other article, whether used alone or in combination, ... intended by the manufacturer to be used for human beings for the purpose of:

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

medical device

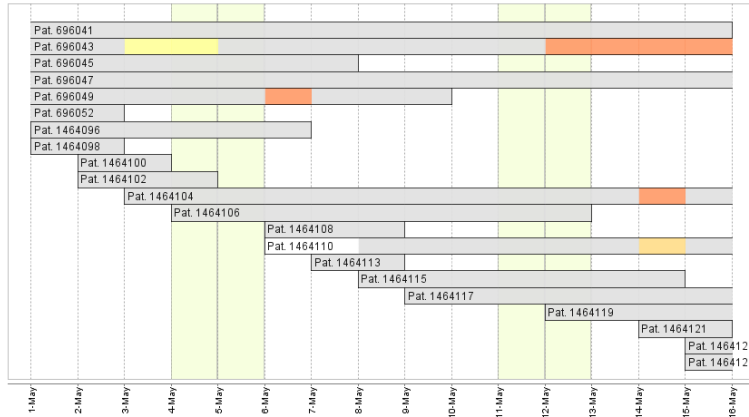
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# ARDENSUITE software: generic technology platform for clinical decision support



from 2013-05-01 to 2013-05-15 show clinic hide department diagram fixed column width

Stat. 39690



stay in hospital  
 stay at department  
 no data  
 10 - 50 %DoC  
 50 - 90 %DoC  
 90 - 100 %DoC  
 100 %DoC

# Moni-ICU: surveillance of healthcare-associated infections

department / patient	Stat. 696043
Stat. 10865	
Stat. 10896	
Stat. 10897	
Stat. 10898	
Stat. 11051	
Stat. 11053	
Stat. 11082	
Stat. 11083	
Stat. 39690	
Pat. 1464096	
Pat. 1464121	
Pat. 1464127	
Pat. 696049	
Pat. 696052	
Pat. 1464108	
Pat. 1464117	
Pat. 696045	
Pat. 1464102	
Pat. 1464110	
Pat. 1464119	
Pat. 1464106	
Pat. 1464100	
Pat. 1464104	
Pat. 1464125	
Pat. 1464098	
Pat. 1464115	
Pat. 696043	

BSI-A (primary sepsis)	
pos. blood culture (t-7d - t)	
pos. blood culture (t-7d - t)	
2013B008329, 2013-05-23 10:00: Blut (zentral): Candida krusei	

BSI-A (primary sepsis)	100 %DoC
PN3 (bact. indication of pneumonia)	100 %DoC
inflamm. symptoms in UTI	100 %DoC
inflamm. symptoms in sepsis	100 %DoC
fever	100 %DoC
hypotension	80 %DoC
high CRP	100 %DoC
leukozytosis	100 %DoC
blood pressure falling	100 %DoC
shock	100 %DoC
high body temperature	100 %DoC
max. body temperature	39 °C
fraction of leukocytes	14.91 G/L
systemic antibiotics	yes
pos. blood culture	100 %DoC
BSI-A (primary sepsis)	100 %DoC
PN3 (bact. indication of pneumonia)	100 %DoC
inflamm. symptoms in UTI	100 %DoC
inflamm. symptoms in sepsis	100 %DoC

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

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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	
<b>BSI-3 (alert) 100 %DoC</b>	
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**



## **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.
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