

Challenges to clinical decision support (CDS)

- 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 (documentation)
 - insufficient data/semantic interoperability (data and terminology standards)
- financial
 - insufficient funds (often not true!)

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

Regulatory framework for clinical decision support software: Present uncertainty and prospective proposition

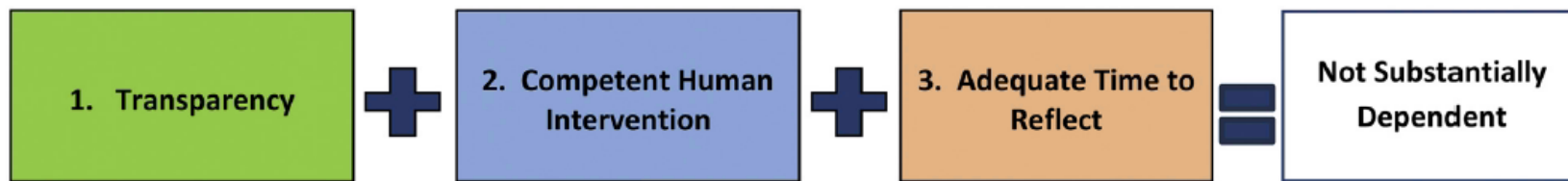
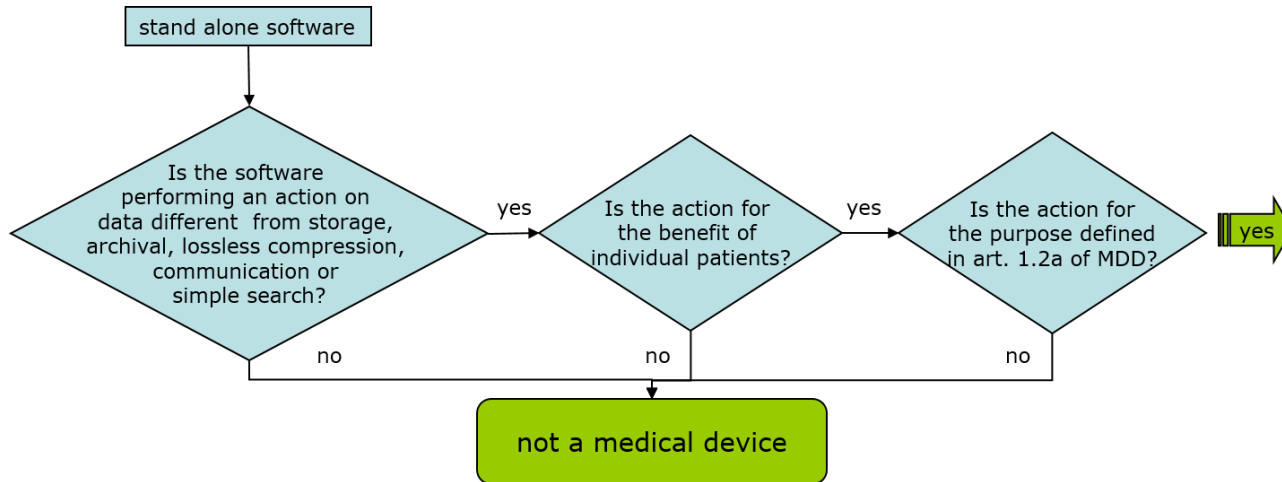


Fig 1. The “substantial dependence” standard.

From Y. Tony Yang and Bradley Merrill Thompson (2015) Journal of the American College of Radiology.

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)

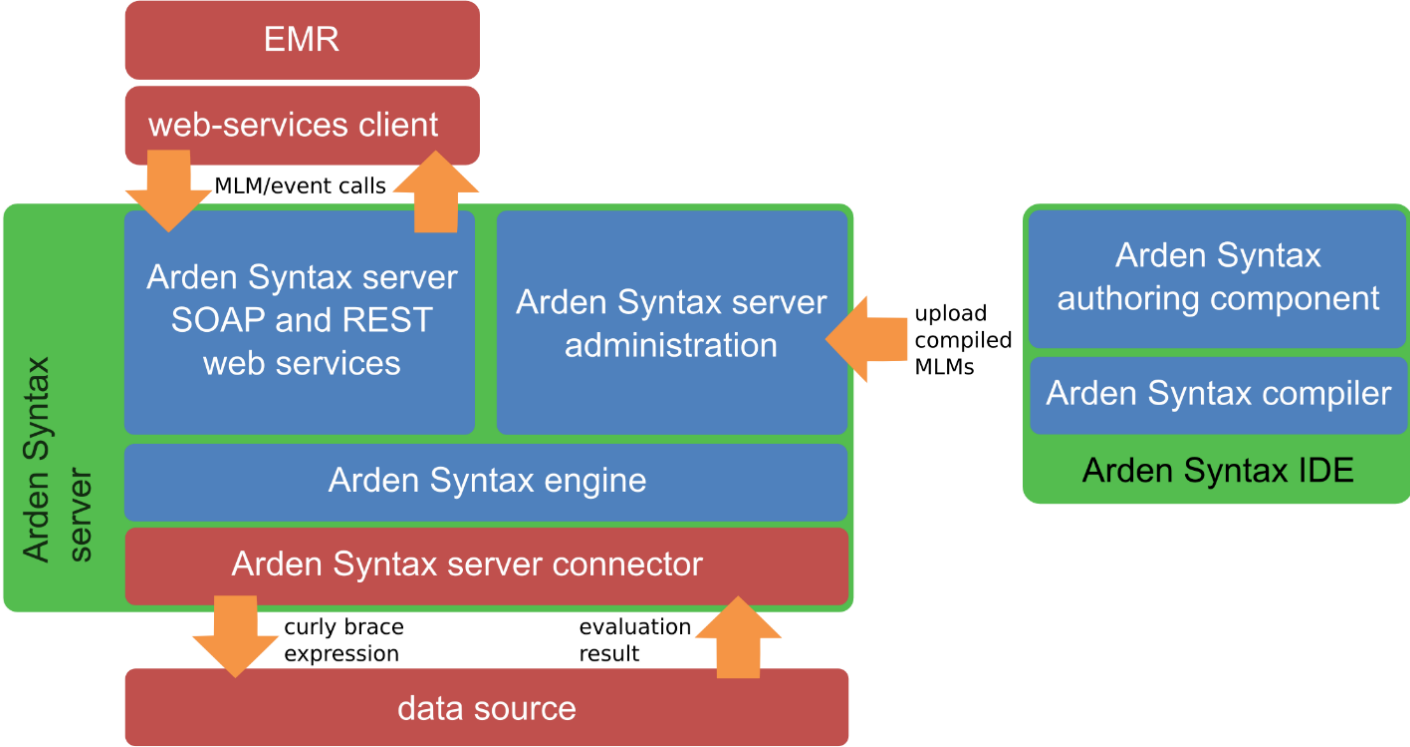
Article 1, Paragraph 2a (art. 1.2a of MDD):

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
- ...

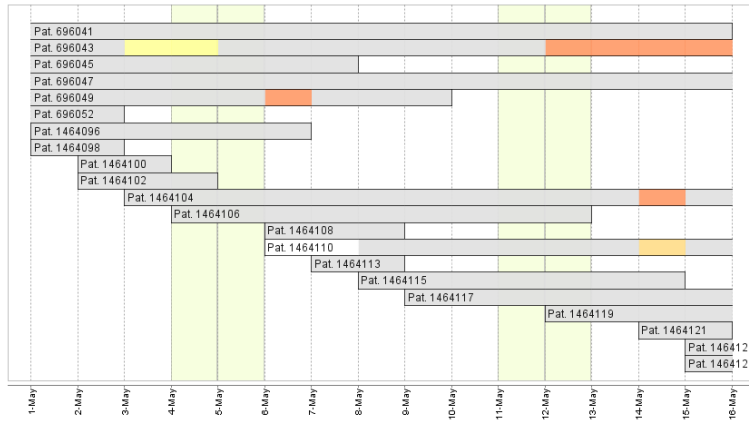
medical device

ARDENSUITE software: generic technology platform for clinical decision support



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	BSI-A (primary sepsis)	pos. blood culture (t-7d - t)
Stat. 10865	2013-06-02 not at ICU		
Stat. 10896	2013-06-01 not at ICU		
Stat. 10897	2013-05-31 not at ICU		
Stat. 10898	2013-05-30 not at ICU		
Stat. 10898	2013-05-29 not at ICU		
Stat. 11051	2013-05-28 (Stat. 39690)		
Stat. 11053	2013-05-27 (Stat. 39690)		
Stat. 11082	2013-05-26 (Stat. 39690)		
Stat. 11083	2013-05-25 (Stat. 39690)		
Stat. 39690	2013-05-24 (Stat. 39690)		
Pat. 1464096	BSI-A (primary sepsis)	100 %DoC	
Pat. 1464121	PN3 (bact. indication of pneumonia)	100 %DoC	
Pat. 1464127	inflamm. symptoms in UTI	100 %DoC	
Pat. 696049	inflamm. symptoms in sepsis	100 %DoC	
Pat. 696052	fever	100 %DoC	
Pat. 1464108	hypotension	80 %DoC	
Pat. 1464117	high CRP	100 %DoC	
Pat. 696045	leukozytosis	100 %DoC	
Pat. 1464102	blood pressure falling	100 %DoC	
Pat. 1464110	shock	100 %DoC	
Pat. 1464119	high body temperature	100 %DoC	
Pat. 1464106	max. body temperature	39 °C	
Pat. 1464100	fraction of leukocytes	14.91 G/L	
Pat. 1464104	systemic antibiotics	yes	
Pat. 1464125	pos. blood culture	100 %DoC	
Pat. 1464098	2013-05-23 (Stat. 39690)		
Pat. 1464115	BSI-A (primary sepsis)	100 %DoC	
Pat. 696043	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

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) 100 %DoC	
AT LEAST 2 OF 100 %DoC	
pathol. heart rate (definition) 100 %DoC	
pathol. Breathing (autom.) 100 %DoC	
pathol. Breathing (autom.) 100 %DoC	
OR 100 %DoC	
tachypnea events increasing 100 %DoC	
increasing breath rate (80%DoC) 54 %DoC	
tachypnea events increasing 100 %DoC	
tachypnoea event (abs.) (t-1d) 1.46 /h	
tachypnoea event (abs.) (Intervall): Max. 3.5 /h	

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

