

# AI Medical Device Software & EU Medical Device Regulation

## BigMed Conference

**Frédéric Courivaud, Dr.Scient., MHA**

19 October 2020

## The New York Times

### Artificial Intelligence Hits the Barrier of Meaning

Machine learning algorithms don't yet understand things the way humans do — with sometimes disastrous consequences.

### *Warnings of a Dark Side to A.I. in Health Care*

BECKER'S  
**HEALTH IT**

### IBM's Watson recommended 'unsafe and incorrect' cancer treatments, STAT report finds

Julie Spitzer - Wednesday, July 25th, 2018 [Print](#) | [Email](#)

## The Boston Globe

### Documents raise alarm over Watson's diagnostic flaws

By Casey Ross and Ike Swetlitz STAT, July 30, 2018, 12:44 a.m.



The “inconvenient truth” about AI in healthcare  
Trishan Panch<sup>1,2</sup>, Heather Mattie<sup>2,3</sup> and Leo Anthony Celi<sup>1,4,5</sup>  
*npj Digital Medicine* (2019)2:77; <https://doi.org/10.1038/s41746-019-0155-4>



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## Changing regulatory landscape



- Updated – wider - definition of a “medical device”
- Re-classification of software to higher risk devices
- More stringent control of Post-Market Surveillance activities
- New requirements for in-house developed devices\*
- Lacking clear guidance for conformity assessment of AI-Medical Device Software

\* Bigmed report: Regulation of Clinical Decision Support Software

## Changing regulatory landscape



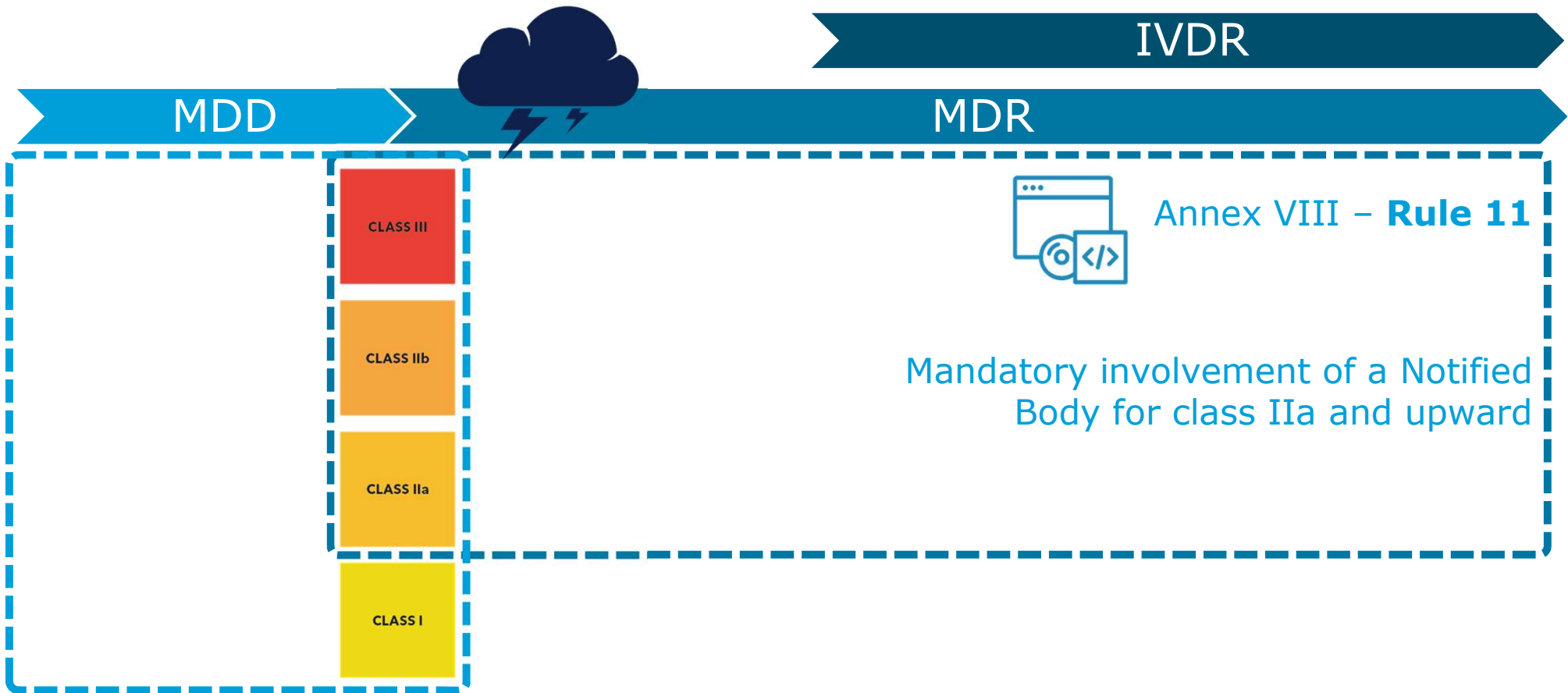
### **Medical device definition - article 2(1) MDR**

*'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*  
*diagnosis, prevention, monitoring, **prediction, prognosis**, treatment or alleviation of disease,*

*diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, And which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. [...];*

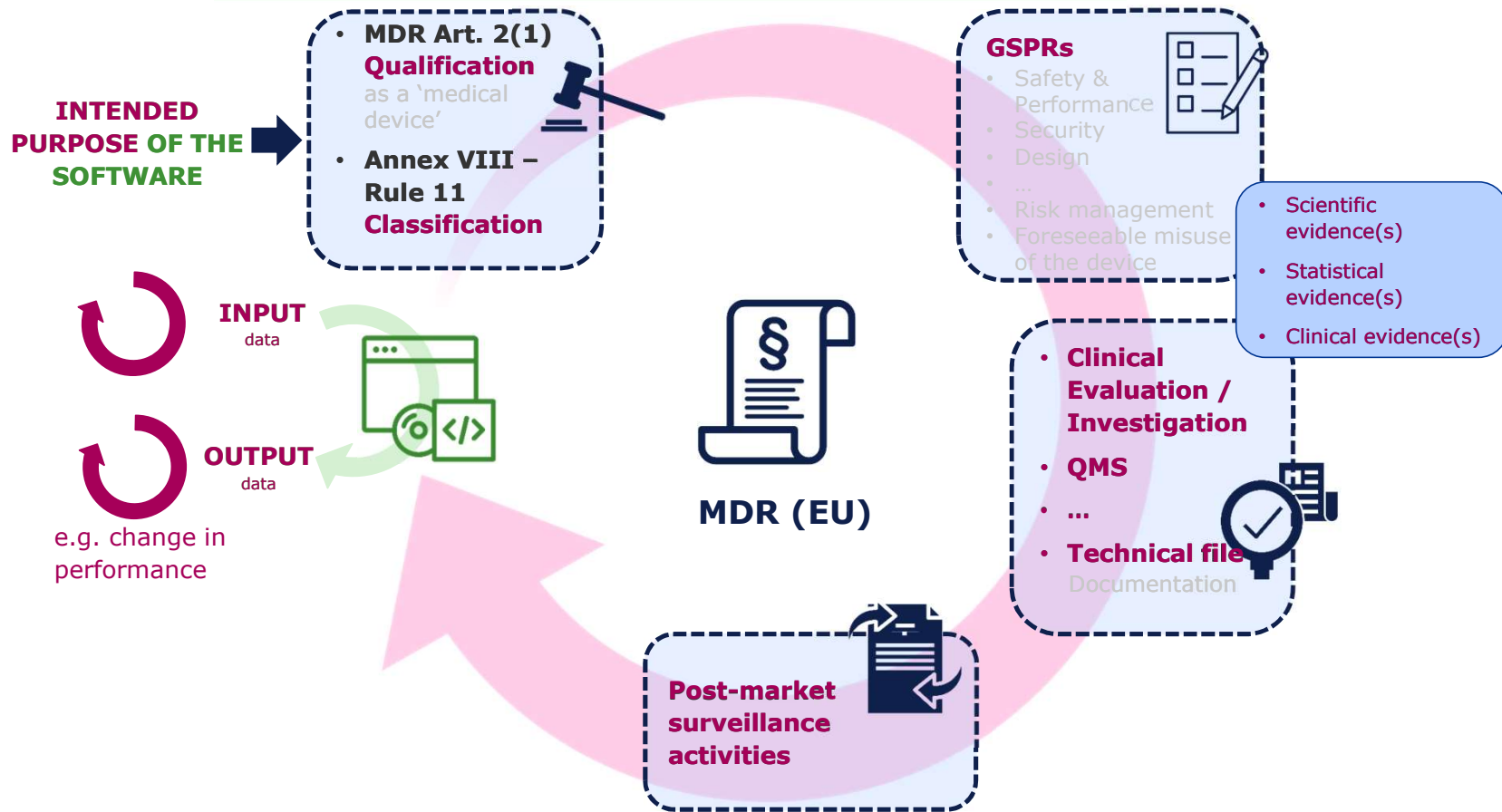
\* Bigmed report: Regulation of Clinical Decision Support Software

## Changing regulatory landscape





## AI-Medical device software





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