How to achieve transparency of evidence and of regulatory reviews for medical devices in the EU?

Lia Crotti, MD, PhD, FESC
IRCCS Istituto Auxologico Italiano and
University Milano Bicocca

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Lancet publication 2018 by Prof. Alan Fraser

The need for transparency of clinical evidence for medical devices in Europe

Alan G Fraser, Eric G Butchart, Piotr Szymański, Enrico G Caiani, Scott Crosby, Peter Kearney, Frans Van de Werf

- **Insufficient transparency from a clinical perspective**
- **We clearly all agree on the importance of transparency**

- To use medical devices rationally, health-care professionals must base their choices of which devices to recommend for individual patients on an objective appraisal of their safety and clinical efficacy.

What type of information we need in the public domain?

- All data? Raw data?
- Only the final report?

- Summary of clinical trials are very important (clinicaltrial.gov)
- All evidence reviewed by notified bodies and regulatory authorities should be disclosed, with the exception, if justified, of technical specifications protected as intellectual property.

- **Which is the purpose of non-full-disclosure?**
- **Commercial purposes?**

- **The evidence submitted by manufacturers when seeking approval of their high-risk devices must be publicly available, including technical performance and premarket clinical studies.**

- **A legal change for the future is proposed in order to have greater transparency**

Is FDA more transparent than Europe?

- Very detailed report
- More transparent
- Quicker approval
- Is a model to follow?

- Difficult to apply that process in Europe
- But access to FDA documents also for European approval could be extremely useful

- **Sometimes devices are approved before publications are out: no control on that**
- **Data should be available!!**
- **So a control mechanism is needed**

Diagnostic devices vs Therapeutic devices

- **Manufacturers clinical regulatory report should be made available for any device both diagnostic and therapeutic device**

CONCLUSION

- We have to insist on having solid evidences available, supported by law changes

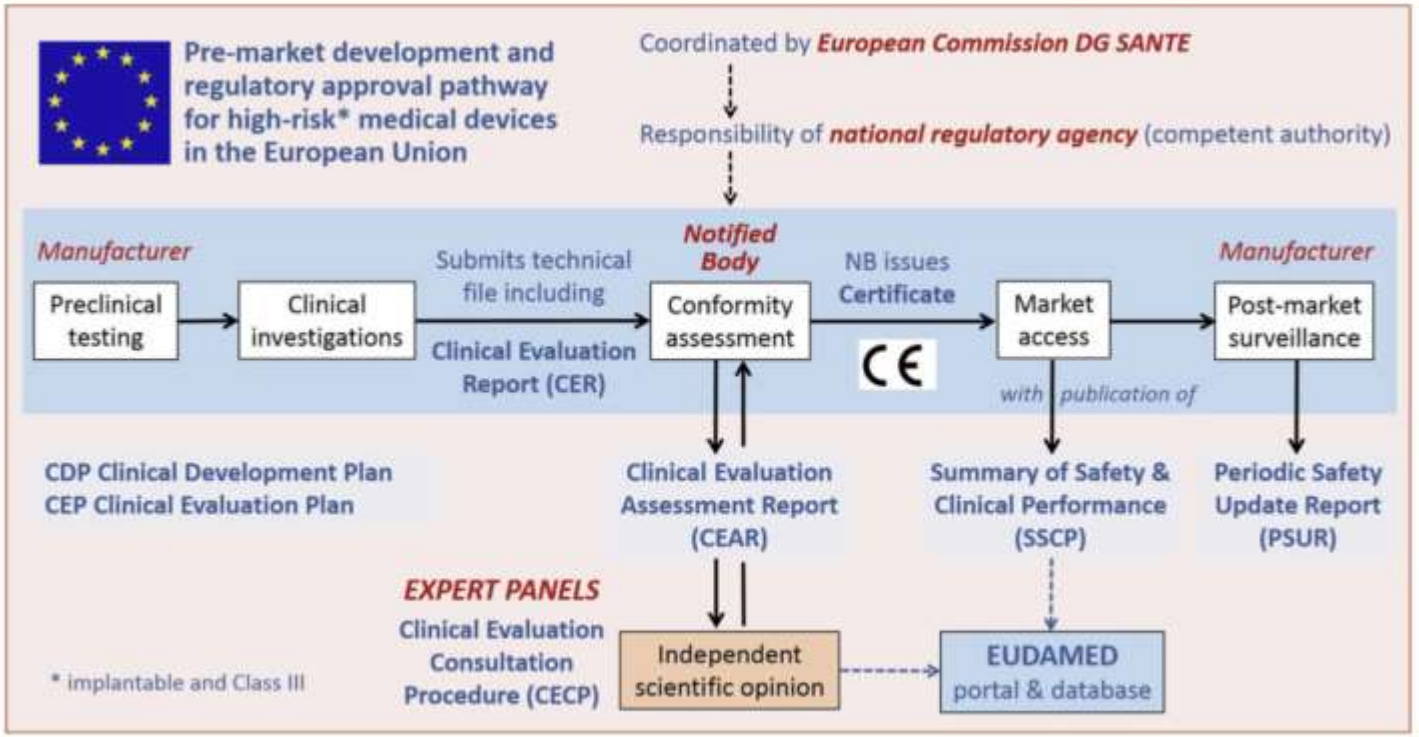
- Full transparency is needed; without it, informed decisions relating to the use of new medical devices will remain impossible.

Thank you!

- **If someone wants to develop new device we need to know where is the best place to develop such a new device**

- **Conflict of interest should be taken into account**

- **The new EU law on medical devices states that the manufacturer is to prepare a summary of the evidence for any implantable or high-risk device. Defining its content, however, has been delegated to implementing legislation, which is now being considered.**



Take home figure Schematic representation of the approval process and the Clinical Evaluation Consultation Procedure for high-risk medical devices. Eudamed, European Union Database on Medical Devices; NB, notified body; DG SANTE, Directorate-General for Health and Food Safety.

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