

PROPOSITIONS

Recommendations for the Safety Surveillance of Medical Devices

- 1) There is a gap between the safety surveillance of medicines and that of medical devices. [this thesis]
- 2) New safety evaluation tools and guidelines should be developed to improve the completeness and quality of the data used in post-market surveillance. [this thesis]
- 3) Post-market surveillance stakeholders should focus on the development and standardization of data sources, signal detection methodologies and coding dictionaries to support the regulatory decision-making process of the new and more dynamic safety surveillance system. [this thesis]
- 4) The proposed post-market surveillance plan template may serve as a thorough tool for the benefit-risk evaluation of medical devices. [this thesis]
- 5) New technologies like blockchain have the potential to support a proactive safety surveillance system for medical devices. [this thesis]
- 6) “Take care of the patient and everything else will follow”. [Thomas Frist]
- 7) “One never notices what has been done; one can only see what remains to be done”. [Marie Curie]
- 8) “The important thing is to never stop questioning”. [Albert Einstein]
- 9) “I have not failed. I’ve just found 10,000 things that won’t work”. [Thomas Edison]
- 10) “Human error is inevitable. We can never eliminate it. We can eliminate problems in the system that make it more likely to happen”. [Liam Donaldson]
- 11) “The main thing in life is not to be afraid to be human.” [Pau Casals]