

IDEAL-D: the preclinical stage (0)

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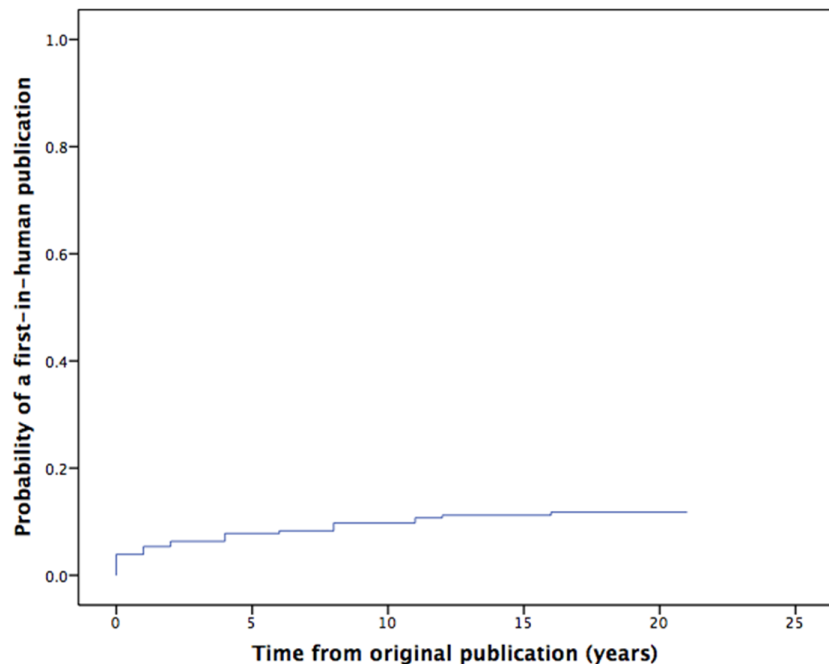
Classification of devices

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The problem



- First-in-human studies are the largest barrier to translation
- First-in-human studies also represent the greatest risk to patients

Aims and objectives



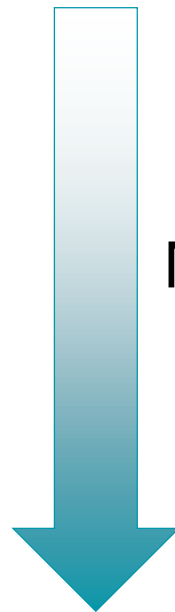
- *What* the device does and *how* it does it?
- *What* the results of preclinical testing show about its success in doing so?

Classification of devices



Classification of devices

- Non invasive
- Invasive (non surgical)
- Surgical instruments
- Absorbable surgical implants
- Non-absorbable surgical implants



More invasive

*Software?!

Classification of studies

Surveys

Laboratory studies

Unmet needs analyses

Animal studies

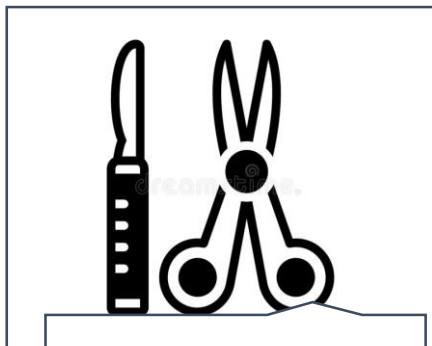
Cadaver studies

Interaction analyses

Focus groups

Economic analyses

Classification of studies



Device

- Safety
- Effectiveness



Clinician

- Usability



Patient

- Acceptability



System

- Necessity
- Relevance
- Viability

Recommendations – A proportionate response



- Communicating about any ideas which were tried and abandoned
- Conducting studies in all relevant fields of interest
- Testing the reliability and technical effectiveness
- Supplying information to the patient

Conclusion

- Stage 0 is important
- Classification of devices and study types has been helpful
- Recommendations are proving challenging but principles are established
- Open to suggestions!