Drug Development for Academics

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➢What not to do

- 'Damning' FDA inspection report undermines positive trial results of possible Alzheimer's drug
  - https://www.science.org/content/article/damning-fda-inspection-report-undermines-positive-trial-results-possible-alzheimer-s

➢Protect Before You Publish: Secure Your Innovation, Advance Your Impact

- https://www.wipo.int/en/web/technology-transfer#:~:text=Technology%20transfer%20supports%20the%20life,development%20collaboration%20or%20licensing%20deals
- https://autm.net/about-tech-transfer/what-is-tech-transfer

➢If It's Not Documented, It Didn't Happen

- Bolon B et al. Good Laboratory Practice in the Academic Setting: Fundamental Principles for Nonclinical Safety Assessment and GLP-Compliant Pathology Support When Developing Innovative Biomedical Products. ILAR J. 2018;59(1):18-28.
- Muller-Ruch U et al. GLP: A requirement in cell therapies - perspectives for the cardiovascular field. Adv Drug Deliv Rev. 2020;165-166:96-104.

➢Talk to the real experts

- Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-pdufa-products

➢Beyond mechanism: Regulatory value of nonclinical studies

- ICH M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m3r2-nonclinical-safety-studies-conduct-human-clinical-trials-and-marketing-authorization
- Strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products - Scientific guideline
  - https://www.ema.europa.eu/en/strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational-medicinal-products-scientific-guideline
- van Gerven J, Bonelli M. Commentary on the EMA Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products. Br J Clin Pharmacol. 2018 Jul;84(7):1401-1409. doi: 10.1111/bcp.13550. Epub 2018 May 30. PMID: 29451320; PMCID: PMC6005602.

➢Strong science is always required: Experimental design, statistical analysis, reporting

- Blainey P et al. Points of significance: replication. Nat Methods. 2014;11(9):879-80.
- Lazic SE et al. What exactly is 'N' in cell culture and animal experiments? PLoS Biol. 2018;16(4):e2005282.
- Percie du Sert N et al. The ARRIVE guidelines 2.0: Updated guidelines for reporting animal research. PLoS Biol. 2020;18(7):e3000410.
- Vollert J et al. Systematic review of guidelines for internal validity in the design, conduct and analysis of preclinical biomedical experiments involving laboratory animals. BMJ Open Sci. 2020 Apr 15;4(1):e100046. doi: 10.1136/bmjos-2019-100046. PMID: 35047688; PMCID: PMC8647591.

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