DRUG / DEVIVE DEVELOPMENT COURSE

Reference Course Material

DRUGS - GENERAL

1. <https://mtz-clinical.pl/wp-content/uploads/2018/08/guidelines-for-phase-i-clinical-trials-2018-edition-20180626.pdf>
2. <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug>
3. <https://www.fda.gov/forpatients/approvals/drugs/ucm405622.htm>
4. <https://ec.europa.eu/health/documents/eudralex_en>
5. <https://www.ich.org/home.html>
6. <https://www.ncbi.nlm.nih.gov/books/NBK92015/>
7. <https://www.fda.gov/training-and-continuing-education/fda-learning-portal-students-academia-and-industry>
8. <https://www.ivowen.com/regulatory-affairs-common-abbreviations-acronyms/> ABBREVIATIONS).
9. <https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1111/cts.12567> GOOD on mAb
10. <https://www.nuventra.com/resources/blog/path-to-ind-study-design-and-dosing/>
11. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6342261/> (FIH GOOD)
12. [CDER Small Business & Industry Assistance (SBIA) | FDA](https://www.fda.gov/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia)
13. [European Medicines Agency - YouTube](https://www.youtube.com/user/emainfo/videos?app=desktop)

**STARTING DOSE IN HUMANS**:

1. <https://www.ema.europa.eu/en/documents/presentation/calculation-minimum-anticipated-biological-effect-level-mabel-1st-dose-human-jennifer-sims_en.pdf>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4804402/> Dose calculation.
3. <http://www.lasa.co.uk/PDF/LASA-NC3RsDoseLevelSelection.pdf>
4. [Strategies for selecting the first dose for human clinical tri.indd (certara.com)](https://www.certara.com/app/uploads/2020/12/Strategies-for-selecting-the-first-dose-for-human-clinical-tri.pdf)

EARLY STAGE START-UPS :

1. [FDA: Orientation for Early Stage Startups (ycombinator.com)](https://blog.ycombinator.com/fda-orientation-for-early-stage-startups/) GOOD QUICK OVERVIEW FOR START-UPS

CMC:

1. [The Challenge of CMC Regulatory Compliance for Biopharmaceuticals - John Geigert - Google Books](https://books.google.ch/books?id=HAmXDwAAQBAJ&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false) (GOOD CMC COVERAGE)

mAb:

1. <https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1111/cts.12567> (on mAb)

PRECLINICAL:

1. [From Bench to Clinic - The Chronology of Preclinical Studies - ITR Laboratories Canada Inc.](https://www.itrlab.com/from-bench-to-clinic-the-chronology-of-preclinical-studies/)
2. <https://www.nuventra.com/resources/blog/path-to-ind-study-design-and-dosing/>
3. <https://hrcak.srce.hr/file/166090> Dose calculation.
4. <https://journal.emwa.org/preclinical-studies/an-introduction-to-little-known-aspects-of-nonclinical-regulatory-writing/> Click to download

MANAGING CULTURAL DIVERSITY :

1. <https://www.youtube.com/c/MultiCulturalBusinessSolutions> (Week 6 Lionel Laroche).

CLINICAL TRIAL REGULATIONS IN EU:

1. <https://youtu.be/GXEVYUdbkcs> (CTR and CTIS by Irish HPRA)…..Good.

IVDR:

1. <https://youtu.be/1x1pVBe_oK8> (IVDR HPRA).

CTIS :

1. <https://youtu.be/rrld9_JLIIs> (CTIS)
2. <https://youtu.be/xxpc-HPKN28> (Statistics)….
3. <https://youtu.be/MD0cl_SIQrg> (Regulatory Science EMA)
4. <https://youtu.be/GXEVYUdbkcs> (CTR HPRA Ireland Webinar)
5. <https://youtu.be/6_G_o1KPYyk> (Birth of the Pharmaceutical industry
6. <https://youtu.be/Oq0zUVyF1Tc> (EMA FDA Parallel Scientific Advice).
7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6342261/> (Good article starting dose)
8. <https://toolbox.eupati.eu/resources/setting-the-first-in-human-dose/>
9. [How to Determine First-in-Human Dose for Clinical Studies (nuventra.com)](https://www.nuventra.com/resources/blog/determining-first-in-human-dose/)
10. [Strategies and Recommendations for Using a Data‐Driven and Risk‐Based Approach in the Selection of First‐in‐Human Starting Dose: An International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) Assessment - Leach - 2021 - Clinical Pharmacology &amp; Therapeutics - Wiley Online Library](https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.2009)
11. [**https://ispe.org/pharmaceutical-engineering/march-april-2017/eu-clinical-trials-regulation-application-process**](https://ispe.org/pharmaceutical-engineering/march-april-2017/eu-clinical-trials-regulation-application-process)
12. <https://www.advarra.com/blog/understanding-the-eu-clinical-trials-regulations-updates/> (New and good)

MEDICAL DEVICE - GENERAL

1. <http://www.imdrf.org/> DEVICES
2. <https://toolbox.eupati.eu/resources/types-of-study-in-early-clinical-development/> (Preclinical GOOD)
3. <https://youtu.be/zqLkBeGp8g8> (FDA Dose finding good overview.)
4. <https://youtu.be/6TyRktLsL5o> (FIH FDA GOOD OVERVIEW)

INTELLECTUAL PROPERTY RIGHTS

1. [Intellectual Property (efpia.eu)](https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/#:~:text=Pharmaceutical%20intellectual%20property%20(IP)%20%E2%80%93,areas%20of%20unmet%20medical%20need.)
2. [IP - IFPMA](https://www.ifpma.org/subtopics/ip-2/)