morula health

Journey to IND

Supporting document

ICH GCP IB Guidance:

CTD sections needed for an IND:

Module 2.6 - Nonclinical Written and Tabulated Summaries

2.6.1 Introduction
2.6.2 Pharmacology written summary
2.6.3 Pharmacology tabulated summary
2.6.4 Pharmacokinetic written summary
2.6.5 Pharmacokinetic tabulated summary
2.6.6 Toxicology written summary
2.6.7 Toxicology tabulated summary

Module 4 - Nonclinical Study Reports

4.2 Study reports
4.2.1 Pharmacology
- *Primary pharmacodynamics*
- *Secondary pharmacodynamics*
- *Safety pharmacology*
- *Pharmacodynamic drug interactions*

4.2.2 Pharmacokinetics
- *Analytical methods and validation reports*
- *Absorption*
- *Distribution*
- *Metabolism*
- *Excretion*
- *Pharmacokinetic drug interactions*
- *Other pharmacokinetic studies*

4.2.3 Toxicology
- *Single dose toxicity*
- *Repeat dose toxicity*
- *Genotoxicity*
- *Carcinogenicity*
- *Reproductive and developmental toxicity*
- *Local tolerance*
- *Other toxicity studies*

4.3 Literature references

CTD Modules (FDA Breakdown):

BioCelerate Nonclinical Report Templates

TransCelerate Common Protocol Template