

BIJLAGE 1 : definitie early-phase studie

In this circular letter, one should consider to be early-phase trials :

- exploratory clinical trials (microdose – phase 0)
- phase I trials
- phase II trials :
 - o first exposure to patients
 - o exploring therapeutic effect / maximum tolerated dose
 - o therapeutic dose finding in patients
- the first administration to children (especially neonates and toddlers)