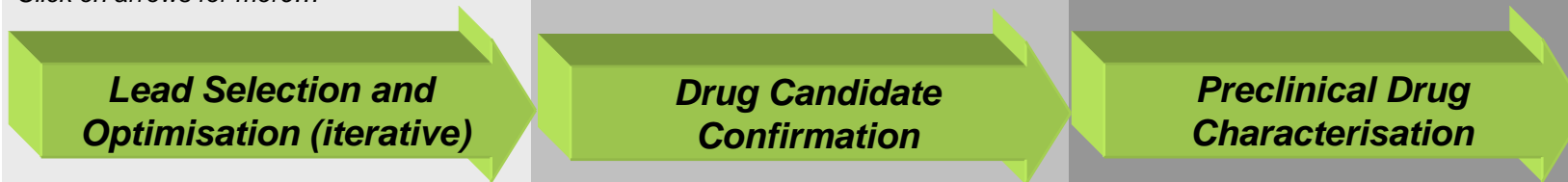


Click on arrows for more...



Efficacy Assessment – “Does it work?”

- Screening disease models (in vitro and in vivo)

- “Benchmark” disease models (human dosing route e.g. oral)

ADME Profiling – “How can it be delivered and what does the body do to it?”

- *In silico profile**
- Simple analytical method
- Membrane permeability
- Plasma stability

- CYP screen
- Microsomes
- Hepatocytes

- Optimised analytical method
- Oral bioavailability
- Basic pharmacokinetics (PK/PD relationship)
- Metabolite profiling

- Validated analytical method
- Comprehensive pharmacokinetics
- GLP toxicokinetics
- Metabolite identification

Toxicology/Safety Pharmacology Assessment - “Is it safe?”

- *Off target screen**
- Cytotoxicity
- Prelim. AMES screening
- *hERG binding**

- Max. tolerated dose
- Repeat dose (7-10 day) in rat
- *Prelim CVS pharmacology (anaesthetised rat)**

- GLP acute toxicology rodents
- GLP subchronic repeat dose rats & dogs
- GLP genotoxicity standard battery
- *GLP Safety pharmacology (CVS, CNS & Respiratory) rat or dog and hERG**

Pharmaceutics – “Is its manufacture viable and controllable?”

- Prototype formulations
- Solubility
- Stability assessment

- Structural characterisation
- preliminary impurity identification and initial analysis

- Formulation for GLP toxicology (suit larger doses, maximise stability, safer solvents etc)
- Detailed physicochemical characterisation (e.g. polymorph identification)
- Further impurity and formulation analysis

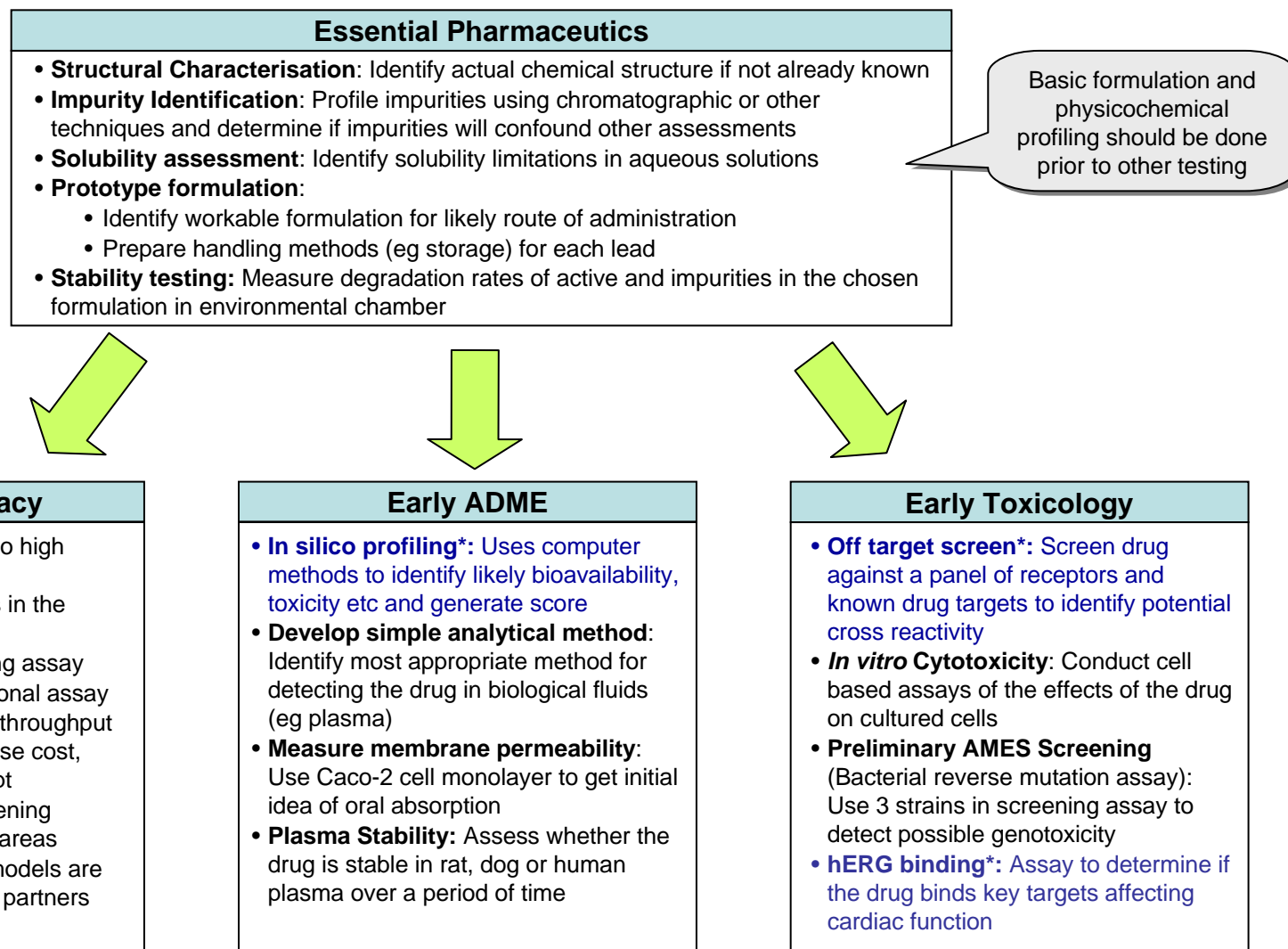
- ICH Stability Testing (drug and product)
- ICH impurity analysis of GLP formulation
- Prototype clinical formulation

Regulatory Submission or Presentation to Pharma

* Note: Items in blue text are either in development by TetraQ provided by partners. All items can be sourced and managed by TetraQ.

Stage 1: Lead Selection and Optimisation

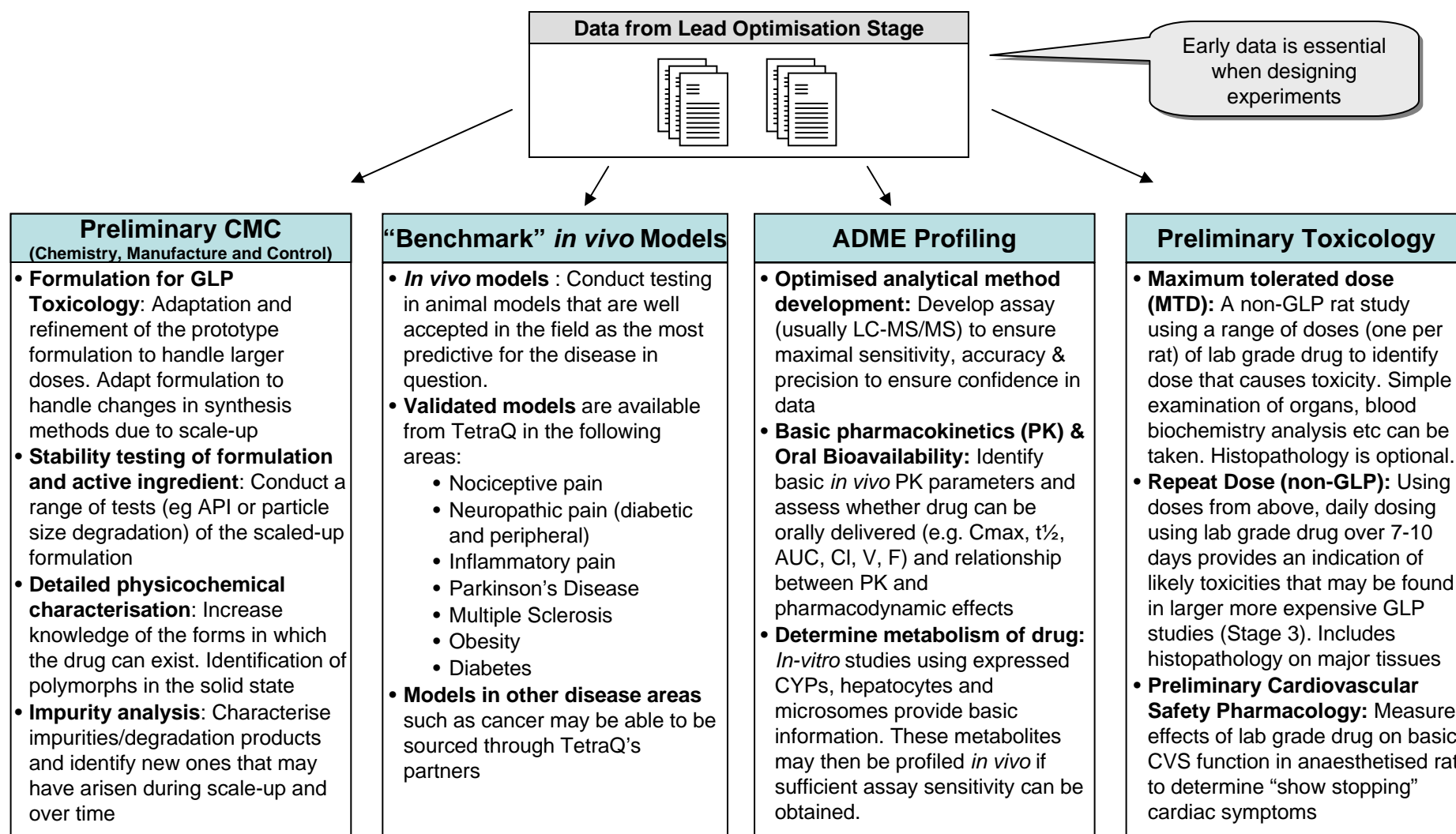
This stage typically involves screening of several or more compounds for efficacy and basic drug-like characteristics. The objective is to provide fast feedback and prioritise the “best” compounds that will be assessed against more detailed criteria in the Candidate Selection stage. These tests are designed to be relatively low cost, with only sufficient accuracy and predictive value to rank compounds for further development.



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Stage 2: Drug Candidate Confirmation

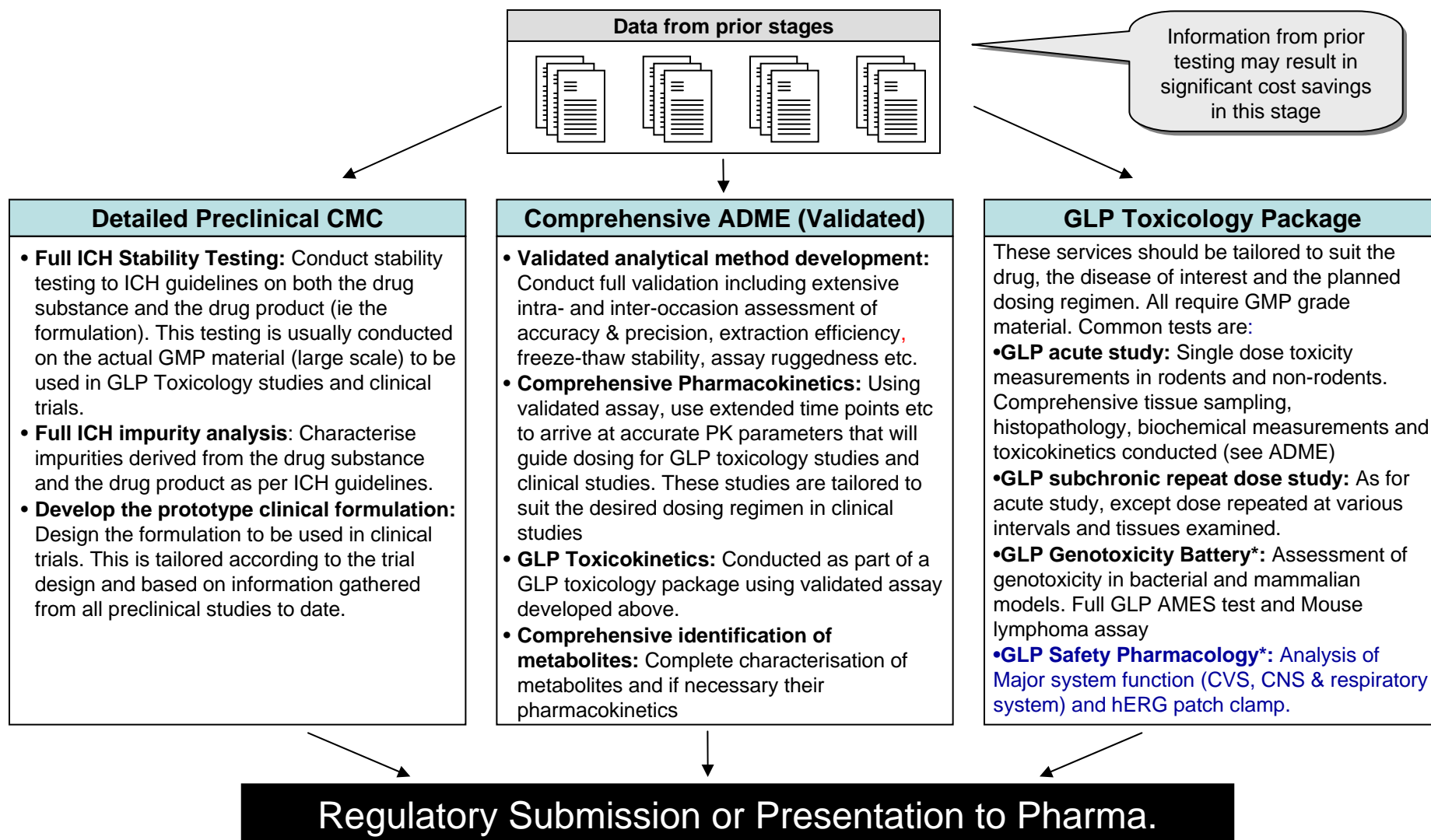
This stage typically involves a more in-depth and accurate application of the tests from the previous stage and adds a broader panel of tests, including some that may be “show stoppers”. It aims to confirm that a compound is worthy of further development without incurring large costs and to guide the most efficient conduct of the next stage. The data generated here is commonly used to meet investment milestones.



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Stage 3: Preclinical Drug Characterisation

This stage is designed to provide highly accurate, reliable data that will be used to justify the conduct of clinical trials. It requires a high level of evidence and documentation to meet the demands of government regulations (eg GLP accreditation) or pharmaceutical companies, and is therefore relatively expensive to conduct. Prudent completion of prior stages will reduce the risk of money being wasted on a poor drug in this stage.



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