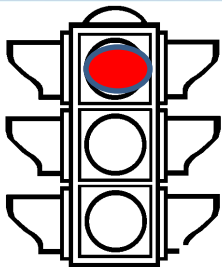


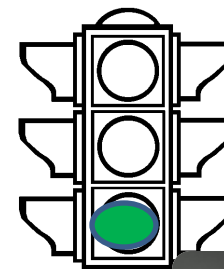
# SMART Development of Pre-Clinical Candidates



**Crystal Pharmatech**  
Your Solid State Research Partner



## Poor understanding of interplay of solid state and biopharmaceutical properties:



◆ When to do a salt screen?

◆ What vehicles to use for PK development?

◆ When to use conventional vs enabled formulations?

◆ When can formulations help and when they cannot?



Amorphous solid dispersions?



Nanomilling?



Surfactants?



Unable to achieve MTD



Unnecessary exotic formulations!



Solubility-limited compounds



Food effect



Too many PK studies!



Dissolution-limited compounds



Low and variable plasma exposures



- ◆ Sound scientific approach to PK formulation development
- ◆ Utilize solid-state and biopharmaceutical properties in design
- ◆ Minimize unnecessary PK studies
- ◆ Design not screen PK formulations
- ◆ Get to decision points faster – know when to cycle back and re-evaluate compound
- ◆ Understand when non-conventional formulation is necessary
- ◆ Quickly rule-in or rule-out salts or co-crystals
- ◆ Understand impact of solid-state every step of the way
- ◆ Clear visibility to FIH studies

Screening

Scale-up

Evaluation  
of hits

Stability  
of lead



- ◆ Proprietary decision trees developed by our SAB and consultants (over 60 years large pharma experience in PK formulations)
- ◆ Armed with latest technology in solubility enhancing vehicles and technologies
- ◆ Minimal “random walk” of toxicology formulation development. No unnecessary PK studies.
- ◆ Offerings tailored to specific project and budget
- ◆ Can seamlessly work with our partners to perform animal studies
- ◆ Opportunity to bring in SAB into project meetings – true one-stop-shop for PK formulation development

**Lead  
Optimization**

Assess all key parameters in a continuous process  
Minimize “kill” number due to formulatability  
Link discovery, early development and process

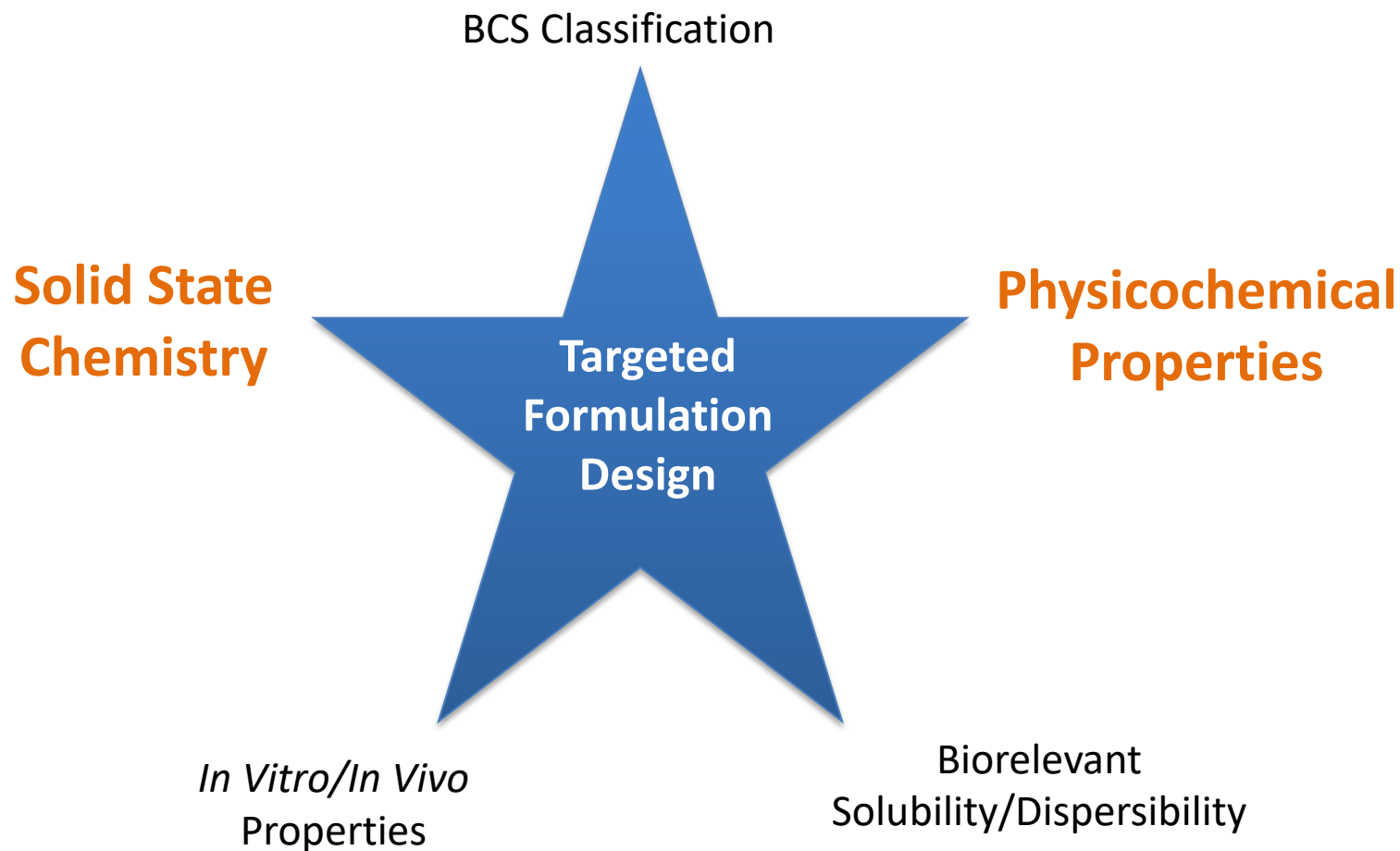
**Development  
Candidate**



# Why Solid Forms for Drug?



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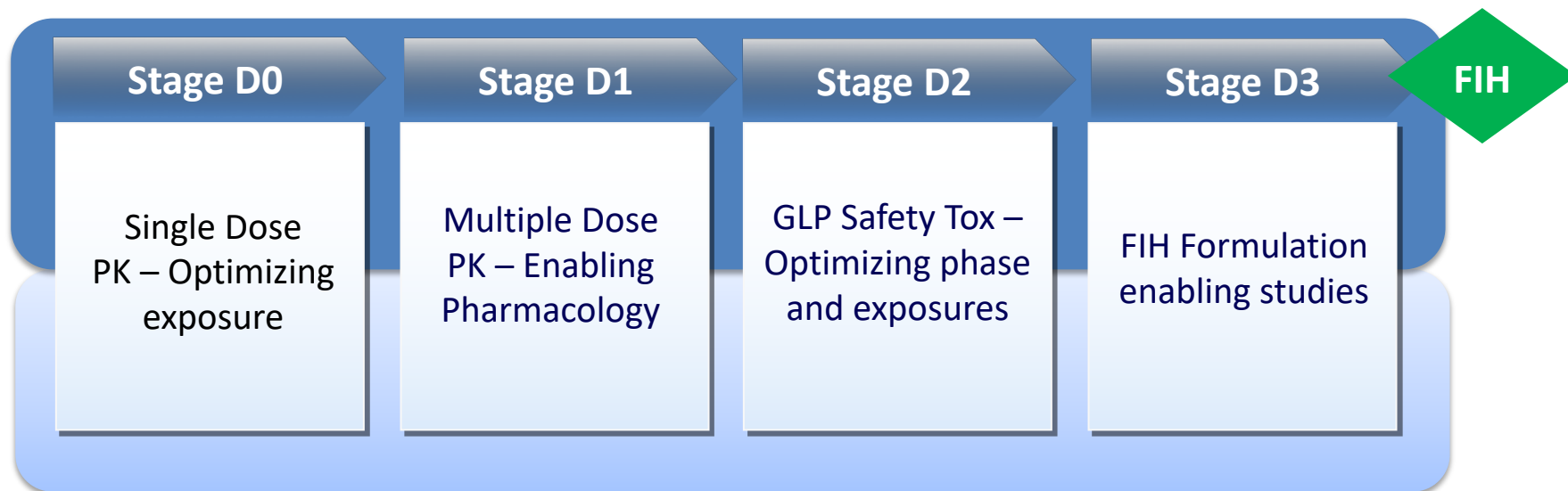


**Design not screen formulations using fundamental solid state and biopharmaceutical properties of your drug compound**

# What Can We Do?



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## *Optimizing Exposure with Single Dose PK Studies*

Finding the right phase and formulation to enhance exposures in a single dose PK experiment

Stage D0

Stage D1

Stage D2

Stage D3

FIH

### Stage D0:

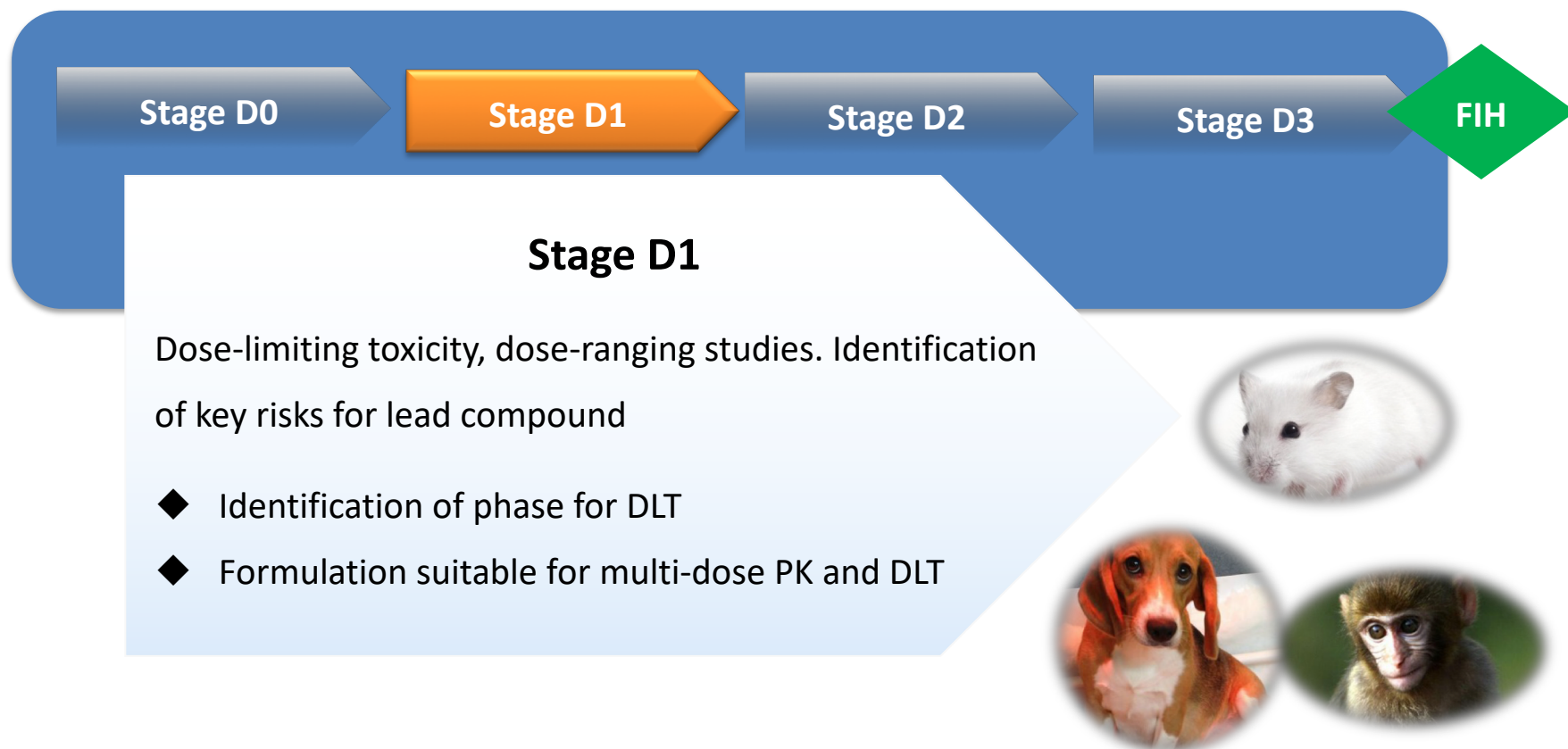
Support of discovery and identification of key risks for lead compound

- ◆ De-risking lead drug compound solid state properties
- ◆ Formulation optimization for single dose oral PK



## *Enabling Pharmacology and Tox Studies*

Finding the right phase and formulation to enhance exposures for pharmacology and toxicity studies



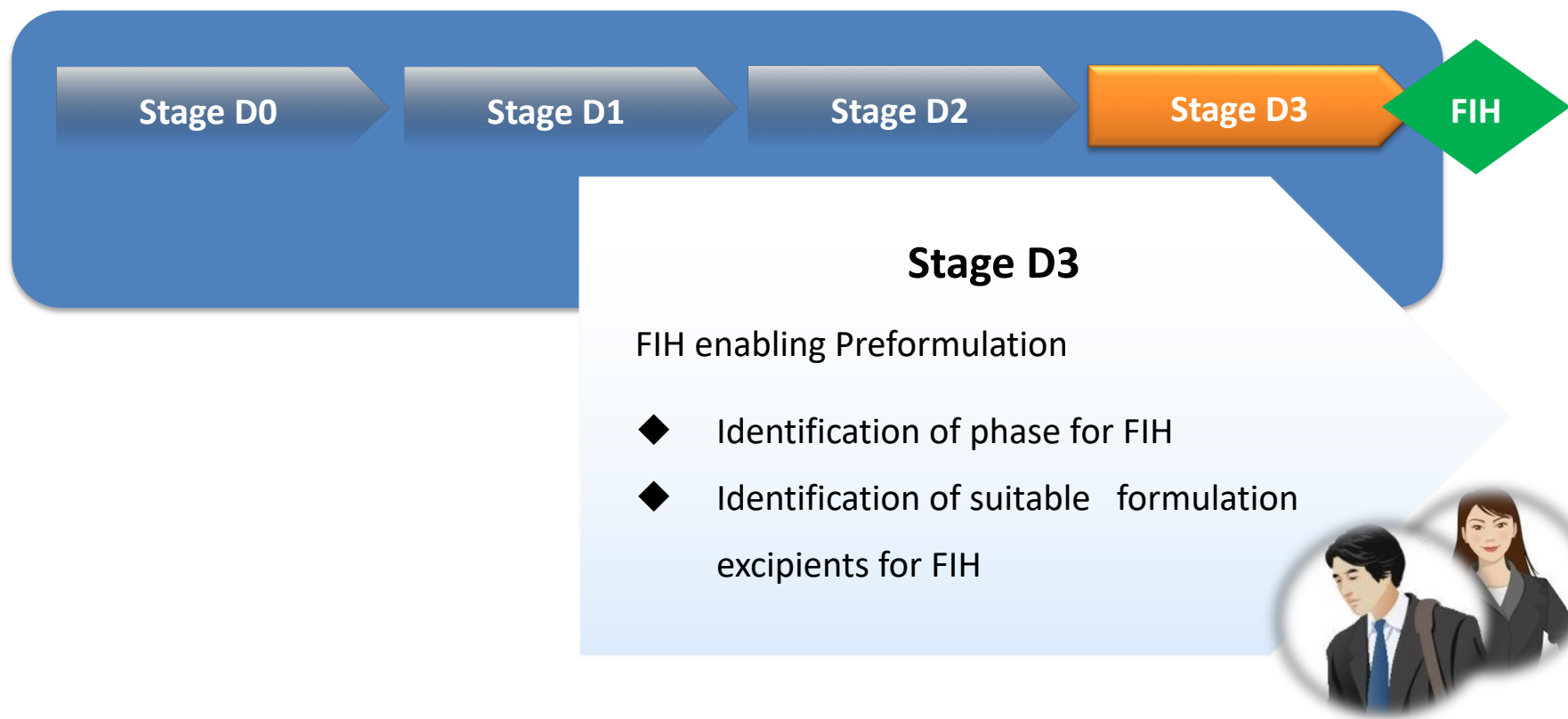
## *Enabling GLP SafetyTox Studies*

Finding the right phase and formulation for GLP Safety Tox to support FIH



## *Enabling GLP SafetyTox Studies*

Finding the right phase and formulation for GLP Safety Tox to support FIH





## *Tailored to Your Specific Needs*

### GOLD

- Complete solid state chemistry phase screening
- Complete physicochemical characterization
- Complete formulation screening

- Final FIH suitable phase
- GLP Safety Tox Formulation

### SILVER

- Partial solid state chemistry phase screening (salt)
- Physicochemical characterization
- Formulation screen for multiple dose PK

- Phase suitable for multidose PK studies
- Formulation for multidose PK studies

### BRONZE

- Rapid screen of physicochemical properties of delivered phase
- Rapid limited formulation screen for single dose PK

- Phase for single dose PK
- Formulation for single dose PK

**Flexible, adaptable, rapid, access to our Scientific expertise**



