Transforming
Promising Molecules

APTrans

into Valued Medicines

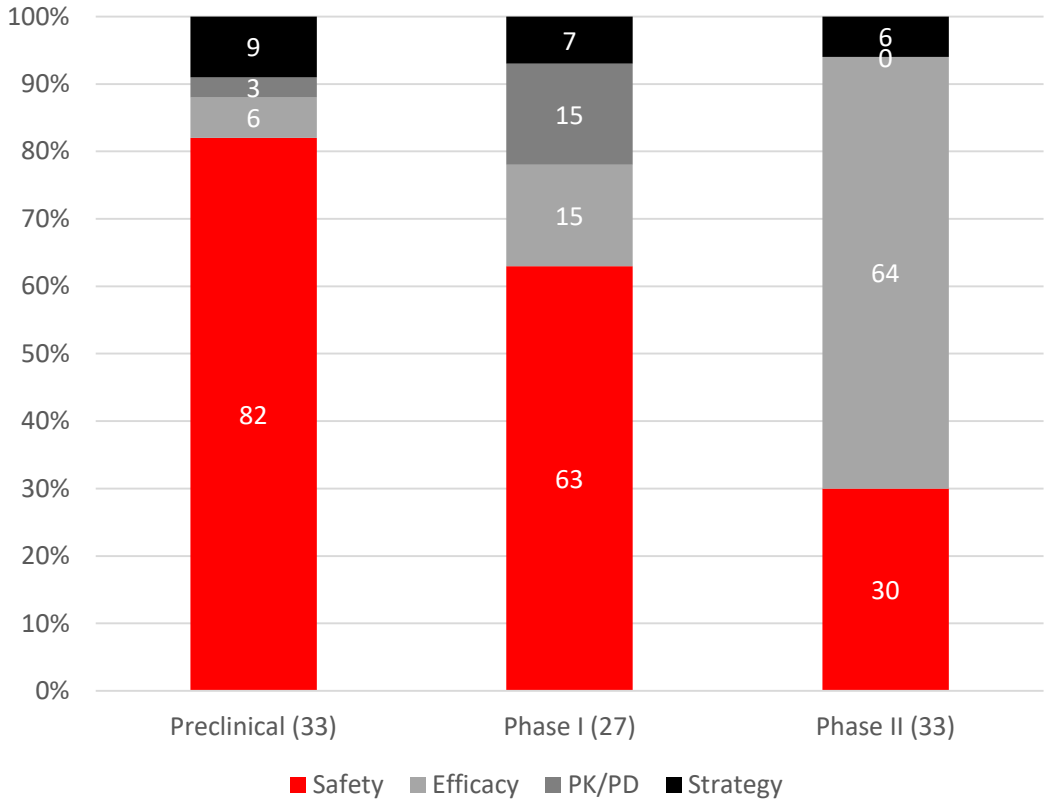
APCONIX
a better decision

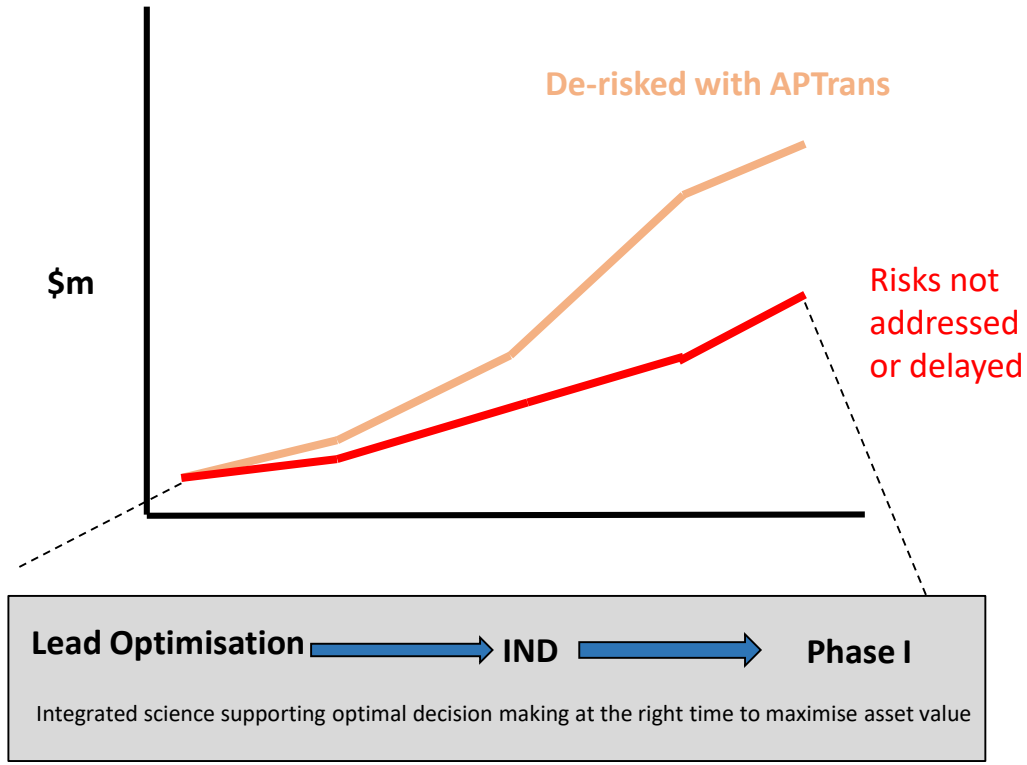
SEDA
Pharmaceutical Development Services

aptusclinical
EXPERTISE DELIVERED FLEXIBLY

Integrated de-risking via APTrans

Primary reasons for project failure 2005-2010 (142 AZ projects)





Cook et al., Nature Reviews Drug Discovery, 13, 2014. Morgan et al., Nature Reviews Drug Discovery, In press, 2018

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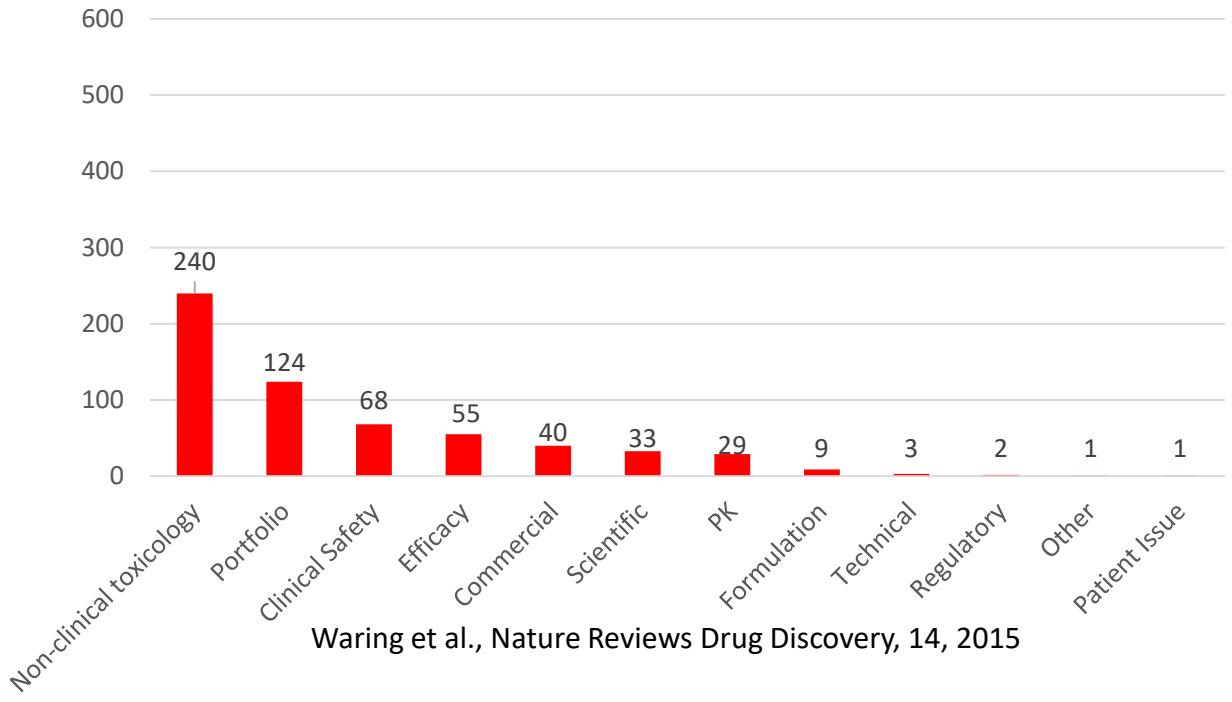
De-risking the ‘Valley of Death’

Primary cause of failure for 605 projects from AZ, Lilly, GSK and Pfizer - 82% stopped due to non-clinical toxicology



Waring et al., Nature Reviews Drug Discovery, 14, 2015

De-risking toxicology:

- **T**arget
  - Target safety assessment to define and mitigate risks
- **C**hemistry
  - Avoiding cardiovascular liabilities such as hERG
  - Early assessment of genetic toxicology
  - PK/PD profile
- **P**atient
  - Appropriate non-clinical safety package tailored to the needs of each project
  - Right patient population

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Ion channel screening and assay development:

Cardiac ion channels and data interpretation

World leading toxicology expertise:

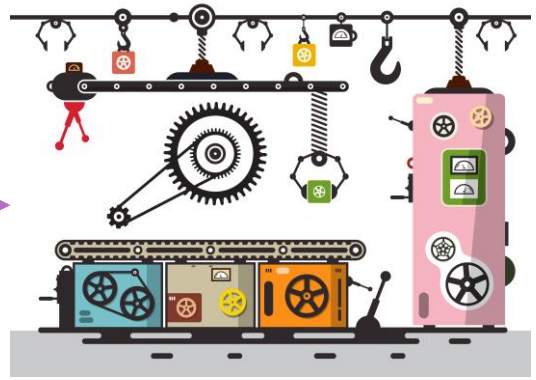
- Target Safety Assessments
- Discovery and Development Project Support
- Due Diligence
- Toxicology Specialists

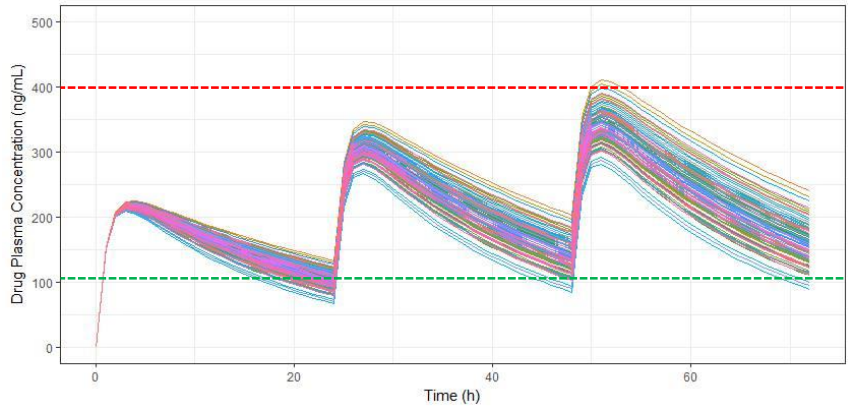
A skilled team providing integrated support from start to finish

ApconiX is a team of world-renowned nonclinical safety experts with over 300 years of drug discovery and development expertise. We will work with you to provide the advice you need, at the right time to make better decisions on drug safety, from project initiation through to worldwide marketing approval

Formulation > Exposure > Safety and Efficacy

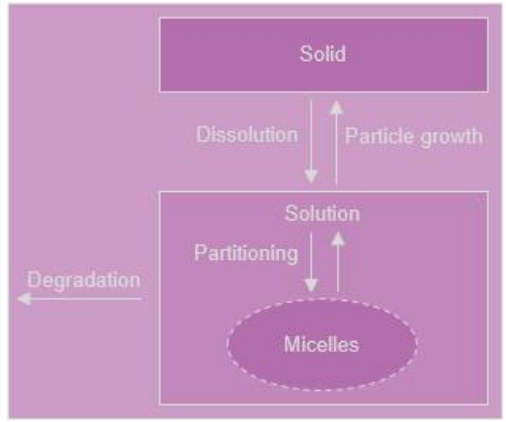
- Need to be able to give the patient something to take!
  - What the patient wants,
    - is willing to take,
    - is easy to take
  - and available when needed

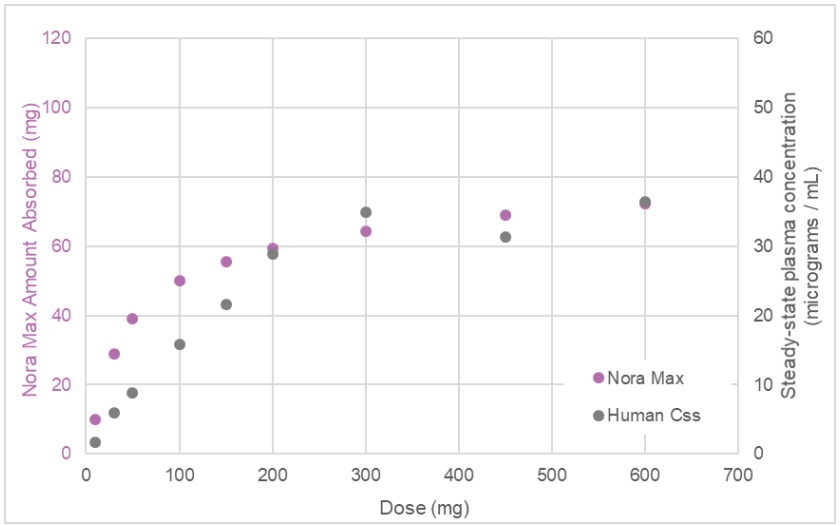


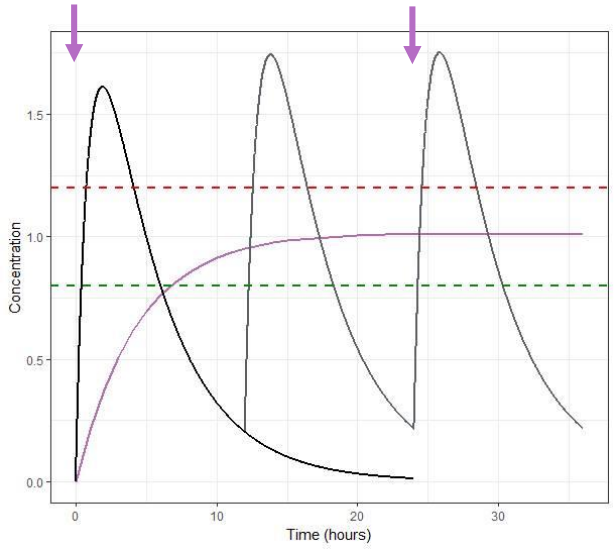


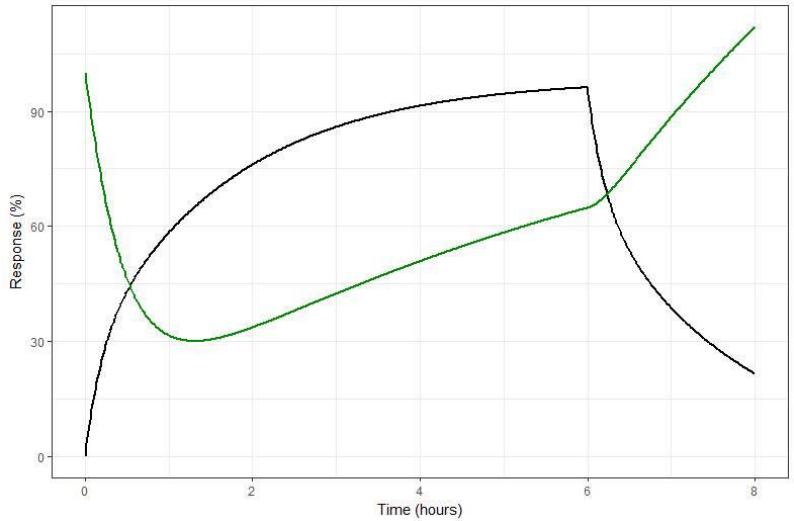
Safety and Efficacy > Exposure > Formulation

- Data modelling to integrate data and mitigate risk
  - The impact of drug properties on drug absorption
  - Relationships between dose, exposure and biological effects
  - Maximises the chance of success in the clinic







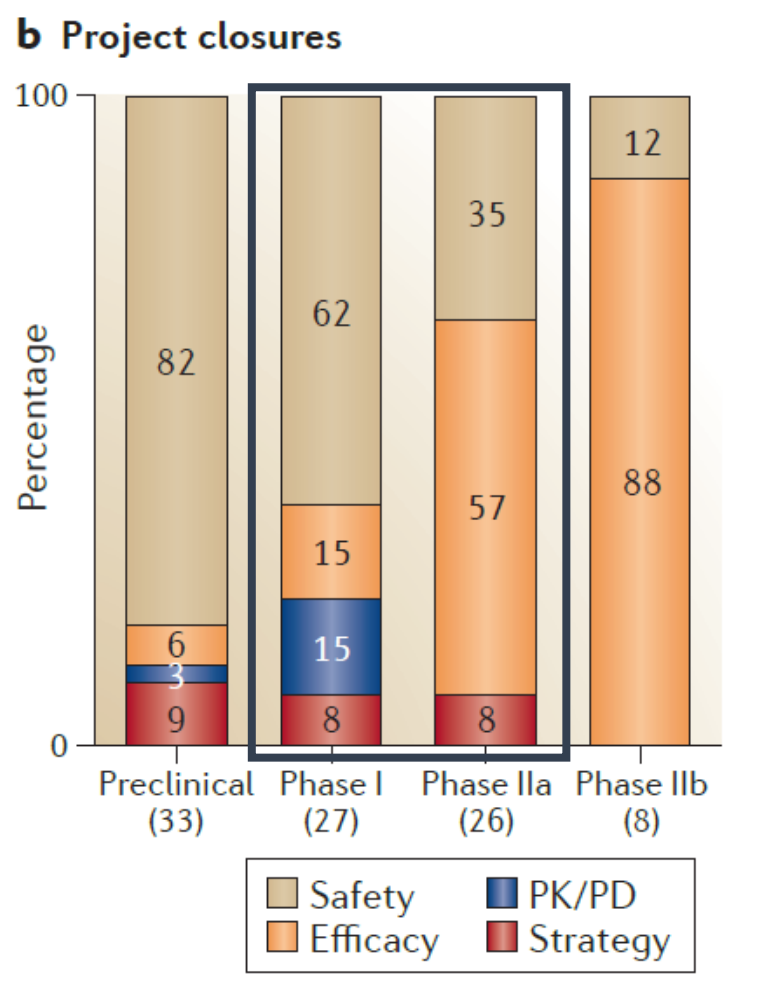


SEDA

Pharmaceutical Development Services

The integrated Pharmaceutical Development and Clinical Pharmacology Consultancy Company that maximises value build

De-risking the valley of death



Cook et al., 2014 Nature Reviews Drug Discovery
http://www.nature.com/nrd/journal/v13/n6/full/nrd4309.html

De-risking clinical points to consider:

- **Choosing the right patients……**
  - Broad patient populations (PK, Safety, tolerability) vs narrow patient populations/biomarker selected patients to reduce efficacy signal/noise ratio
  - Multiple mode of action hypotheses
- **Choosing the right end points…..**
  - Safety and efficacy
  - Pharmacodynamic biomarkers
  - Patient selection biomarkers (multiple hypotheses)
- **Choosing the right study design…..**
  - Traditional vs novel approaches
  - Monotherapy or combination
  - Continuous or intermittent dosing
  - Investigator/patient, ethical, regulatory acceptability
- **Choosing the right development direction…..**
  - Disease and clinical landscape insights to ensure you are meeting patients needs in areas that are valued
  - Selecting clinically relevant patient populations

About Aptus

Founded by experts

Founded in 2014 by 3 former AstraZeneca colleagues with > 75 years combined experience in drug development.

We have a passion for science and in making a difference by helping clients transform their promising molecules into valued medicines

Oncology specialists

Delivered > 100 oncology studies (phase 0-III) in solid tumours and haematology. Work extensively across small molecules, biologics & immuno-oncology, including NDAs, sNDAs and paediatric programmes

Full service CRO

Full range of flexible services based on a mix of in-house experts and our network of carefully selected service partners to ensure global reach, optimise clinical input and expertise, accelerate processes where possible and minimise costs

World class teams

Exceptional clinical development team, with decades of experience delivering global studies. Extensive pharma based expertise and scale across all clinical development areas,

Trusted partners

Our well established relationships with some of the most prestigious investigator sites (e.g The Christie) secures ready access to large patient populations

Growing client list

Portfolio of UK and global clients, ranging in size from large pharma and biotechs, to academic centres and venture capital-backed start ups

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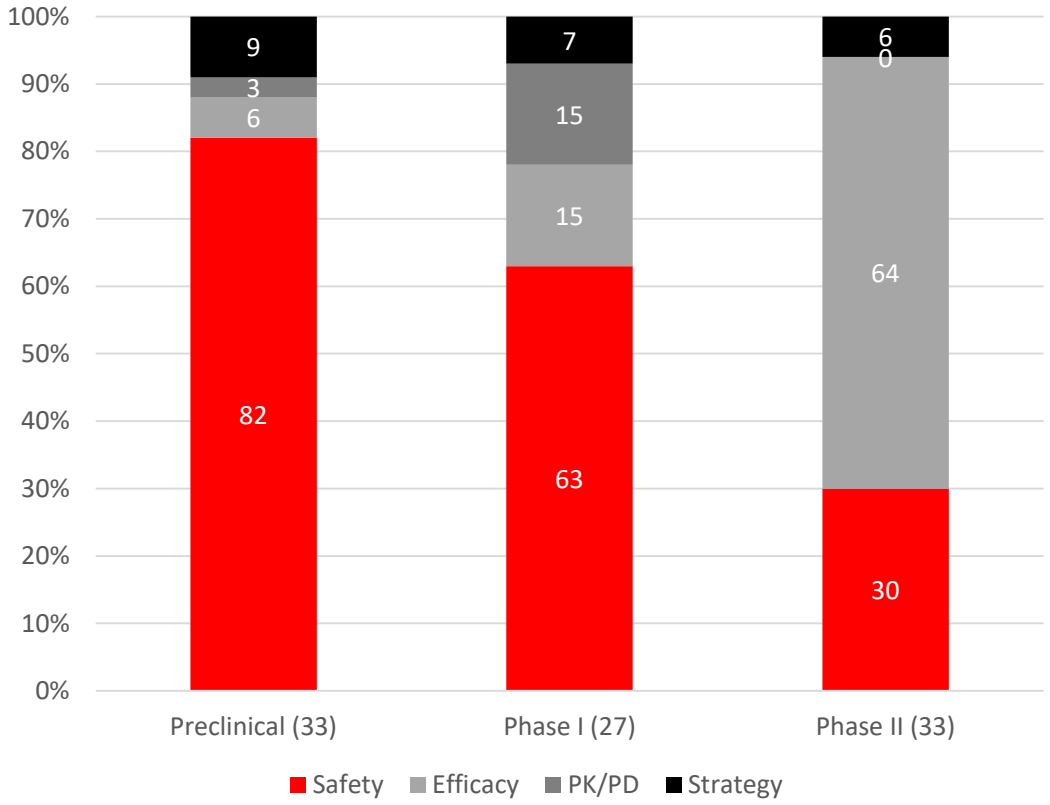

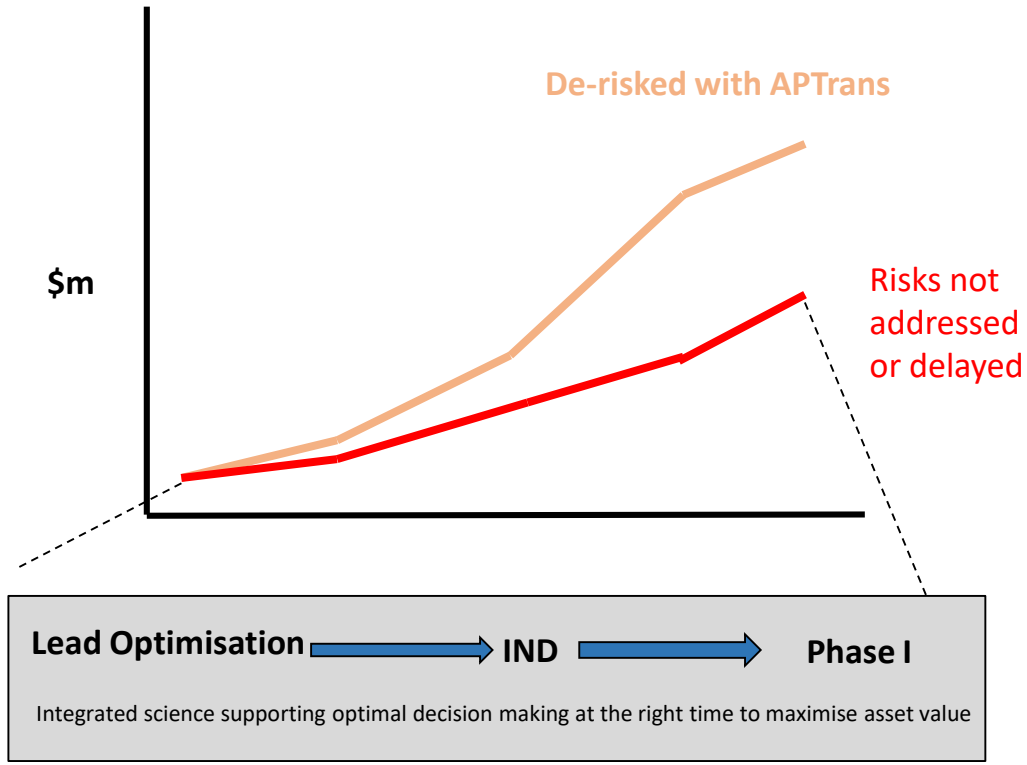

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