Does the envisioned ultimate utility address an unmet clinical need?

Is the work focussed primarily on the discovery/development of the BM for application to clinical material?

Establish a relationship between POM BM result and:
  i) dose and
  ii) plasma/tumour PK
  iii) anti-tumour activity in animal models

BIDD POM BM Discovery – Stage 1

Do you have an assay that measures drug-target interaction?

Establish a relationship between POM BM result and:
  i) dose and
  ii) plasma/tumour PK
  iii) anti-tumour activity in animal models

BIDD POM BM Discovery – Stage 1

Do you have a POC biomarker?

Use POM/POC assay in a small number of clinical samples to ensure assay feasibility

BIDD Assay Development – Stage 2

Investigate relationship between POC BM &:
  i) POM BM results
     (if available)
  ii) dose and
  iii) plasma/tumour PK
  iv) anti-tumour activity in animal models

BIDD POC BM Discovery – Stage 2

Does the distribution of POM/POC BM values indicate assay with clinical utility?

Validate assay to GCLP

BIDD Assay Development – Stage 3

Use POM/POC in Phase I/II clinical trials

Is there a relationship between POM/POC biomarker and:
  i) dose?
  ii) plasma/tumour PK?
  iii) activity/toxicity?

Consider alternative doses or schedules

Can POM/POC biomarker results equivalent to those that equal to anti-tumour activity in preclinical models to be achieved at tolerated doses in patients?

BIDD BM Qualification

Use BM data to inform compound development and clinical trial design

Rationale

Further basic research might be required or redirect research effort elsewhere

Development of an accurate and reproducible assay

BIDD Assay Development – Stage 1

Biomarker Discovery and Assay Development

Biomarker Qualification

Yes

No