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

Is the envisioned ultimate utility address an unmet clinical need?

Further basic research or sample access required, or redirect research elsewhere.

Development of an accurate and reproducible assay to measure BM. BIDD Assay Development – Stage 1

Define BM distribution using the assay on specimens representative of the target patient population. BIDD BM Discovery - Stage 1

Does the distribution of BM values indicate a BM with potential clinical utility?

Refinement of assay: Definition of SOPs and assay performance. BIDD Assay Development – Stage 2

Study the relationship between the BM and clinical outcome retrospectively. BIDD BM Discovery - Stage 2

Is there a correlation between the BM and clinical outcome?

Develop BM assay to appropriate standards. Assay should be fit for purpose. BIDD Assay Development – Stage 3

Validate the correlation between the BM and clinical outcome as a primary or secondary endpoint in a prospective study. CTAAC/BIDD BM Qualification – Stage 1

OR

Define the relationship of the biomarker to clinical outcome in a prospective analysis of a retrospective tissue collection. CTAAC/BIDD BM Qualification – Stage 1

Can the assay or clinical trial design be improved?

Is the correlation between the BM and clinical outcome statistically robust?

Can the assay or clinical trial design be improved?

Undertake clinical trial where the BM defines randomization. CTAAC BM Qualification - Stage 2

Is clinical outcome improved by prospective use of the BM?

Transfer BM to routine clinical practice

Does the correlation between the BM and clinical outcome statistically robust?

Is there a sample collection for retrospective BM-clinical outcome correlation studies (i.e. for BM Discovery – Stage 1/2)?

PROGNOSTIC/PREDICTIVE BIOMARKER (BM) ROADMAP

Rationale

BM Discovery and Assay Development

BM Qualification

Yes

No

Optional