Refinement of assay: Definition of SOPs and assay performance.

BIDD Assay Development - Stage 2

- Develop BM assay to appropriate standards. Assay should be fit for purpose.

BIDD Assay Development - Stage 3

- Define the performance of the BM in comparison to gold standard in a prospective study
  - CTAAC / BIDD BM Qualification - Stage 1

- Is clinical diagnosis improved by prospective use of the BM?

- Transfer BM to routine clinical practice

Bredder BM Discovery and Assay Development

- Does the new biomarker improve diagnostic accuracy?

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

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

- Does the distribution of BM values indicate an assay with potential clinical utility?

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

- Does the envisioned ultimate utility address an unmet clinical need?

- 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

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

Rationale