DIAGNOSTIC BIOMARKER (BM) ROADMAP

- **Rationale**
  - Does the envisioned ultimate utility address & unmet clinical need?
  - Is the work focussed primarily on the discovery/development of a 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)

- **BM Discovery and Assay Development**
  - Development of an accurate & reproducible assay to measure BM
    - BIDD Assay Development - Stage 1
      - Does the distribution of BM values indicate an assay with potential clinical utility?

- **BM Discovery - Stage 1**
  - Define BM distribution using the assay on specimens representative of the target patient population
    - BIDD BM Discovery - Stage 1
      - Refinement of assay: definitions of SOPs & assay performance
        - BIDD Assay Development - Stage 2
          - Study the relationship between the BM & gold standard diagnostic practice using clinical samples collected retrospectively (from clinical trial or cohort)
            - BIDD BM Discovery - Stage 2
              - Does the new biomarker improve diagnostic accuracy?

- **BM Assay Development - Stage 3**
  - Develop BM assay to appropriate standards. Assays 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?

- **BM Qualification**
  - Can the assay or clinical trial design be improved?
    - Yes
      - Transfer BM to routine clinical practice
    - No
      - Further basic research or sample access required, or redirect research elsewhere