**Instructions for Leads**:

Please fill out the charter template below to **plan** and **define** the key aspects of your strategic initiative. The charter will serve as an **executive summary of the nature and scope** of the work on your initiative and **ensures alignment on the expectations of the deliverables (results) with the sponsors** (the BARDS Leadership Team [BLT]). Having a well thought out plan for your strategic initiative is crucial to efficient and successful execution.

Please note that not all fields of the template are applicable to every initiative; please use your judgement to complete relevant fields for your initiative.

**Each strategic initiative’s charter is due by January 31st, 2023.** Leads should author an initial draft following an individual kick-off meeting(s) with Alison, Lisa, and/or Kara. Leads may use the collaboration space provided specifically for their initiative for authoring. Following an initial draft, leads should ensure that key team members have been given the ability to review and provide feedback on the charter before submission. Completed charters should be submitted [here](https://collaboration.merck.com/sites/BARDS-Strategy/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2FBARDS%2DStrategy%2FShared%20Documents%2FCompleted%20Charters&viewid=6de79586%2D876f%2D4152%2D9fc3%2D389480dfaa8c) for review by sponsors (BLT) for directional alignment and sponsor endorsement of the scope, deliverables, milestones, and project teams.

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| --- | --- | --- |
| General Information | | |
| Strategic Priority: | Subgroup Analyses | |
| Lead(s): | Larry Leon | |
| Mission/Vision | | |
| Objective: | Develop principles for performing subgroup analyses for various business purposes | |
| Work Statement: | * Collect and coordinate data on needs for subgroup analysis for different business purposes * Develop principles for how to analyze and interpret the data * Make recommendations on when to use various methods   Notes:   * Need to be mindful of cautions * Need to understand the purpose * What groups do subgroup analyses   + LDS: pre-specify subgroups in SAP; generally use same methods to analyze data. Caution about subgroup interpretation. Need to document uses of subgroup analyses. What is Merck approach here? How does this translate into labelling? Need to do this consistently (both directions).   + EDS: Exploratory/Discovery uses of clinical data (biomarker explorer). Jared working on proposal with appropriate guardrails in place with statistical validation. Also need scientific/biologic validation.   + EDS #2: Subgroup analyses – to find subgroup where drug works/works better or explain why you have a failed trial. May lead to restricted labelling.   + HTA Space: Slice data many ways to answer to payers who want to reimburse in smallest subset of patients. William Malbeqc developed guidance.   + HEDS: Early modelling uses estimates from sample size calculations to determine if product will be reimbursable. Laras idea – is there a subgroup that has higher point estimate of efficacy even if overall doesn’t look favorable? * What methods are best? * Sample size considerations * Cautions still exist and should generate underlying principles (by phase?)   + Need to consider caveats * Need leadership agreement on principles that can span across functions/uses/intrepretations   Step 1: Understand landscape   * Look at William’s guidance * Understand what each group does * Gather data/examples?   + Example from Rob/Thomas: Models failed to converge * Stakeholder analysis (clinical, regulatory, HTA/access space)   Step 2: Bring methods, develop principles, objective assessment   * What are the scientific questions (what/when) to match with methods (how) * Operating characteristics of different methods, interpretability/understanding   Step 3: Review by BLT  Step 4: Implementation/Education (internal and external to BARDS) | |
| Long-Term Vision: | [What does good look like at the end of this project – Intent Statements]   * Objective set of principles (by phase) to be used in subgroup analyses consistently used across BARDS | |
| Scope | | |
| Out of Scope: |  | |
| In Scope: | [Can delete if this would be mutually exclusive with field above] | |
| Touchpoints with other strategic priorities/entities: |  | |
| Key Deliverables | | |
| Deliverable #1 | Work/Project Plan to define needs assessment  Stakeholders, etc | |
| Deliverable #2 | Proposal | |
| Deliverable #3 |  | |
| Deliverable #4 |  | |
| 2023 Milestones | | |
| Milestone #1 | [What is it] | |
| [Targetted Timeframe] | |
| [How to get there – first few steps] | |
| [Other/Additional Information] | |
| Milestone #2 | [What is it] | |
| [Targetted Timeframe] | |
| [How to get there – first few steps] | |
| [Other/Additional Information] | |
| Milestone #3 | [What is it] | |
| [Targetted Timeframe] | |
| [How to get there – first few steps] | |
| [Other/Additional Information] | |
| Milestone #4 | [What is it] | |
| [Targetted Timeframe] | |
| [How to get there – first few steps] | |
| [Other/Additional Information] | |
| Project Team | | |
|  | Name | Primary Role/Responsibility on Team |
| Lead(s): |  | Lead, Project Manager |
| Team Members: |  | Examples (not exhaustive): Lead for substream/deliverable, Reviewer, Subject Matter Expert Consultant (Obtain input on XXX), Piloteer |
| Wei Fu (Darcy’s group) |  |
| Rachel Marceau West |  |
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| Stakeholders: | William Malbecq |  |
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| Types of meetings & Cadence | * Status Meetings (Roles Included, Frequency) * Working Group Meetings (Roles Included, Frequency) | |
| Risk Management | | |
| Potential Constraints/Risks |  | |
| Issue Escalation |  | |