Translational Bridge Award

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Outline

1. Program objectives
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3. The bridge plan
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6. Experience from first cycle
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Lupus Research Alliance

- Largest global non-governmental, non-profit funder of **lupus** research
- Funded over **600** awards, **$265M+** over the last 25 years
- The portfolio evolved throughout the years, with more translational and clinically oriented projects
- Desire to create a competitive, **investigator-initiated** funding mechanism that would reward successful, translationally actionable LRA-funded discoveries, shepherd them towards clinical development
- **Maximize** LRA position at the intersection of academic, clinical, governmental and industry networks

Translation Bridge Award Mechanism

Objectives

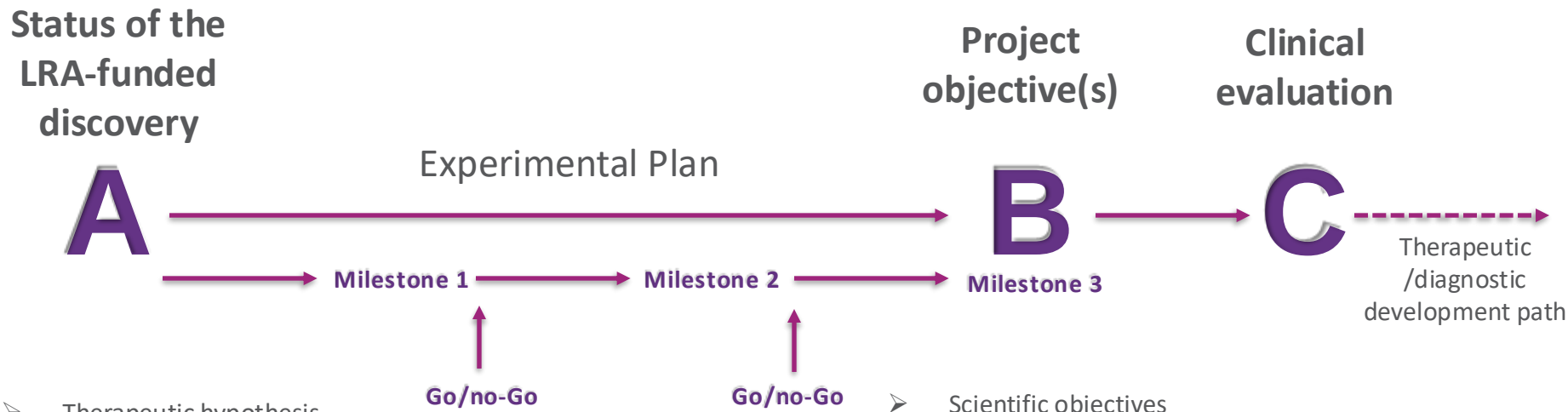
- Provide a dedicated mechanism to bridge the post-discovery to pre-commercial development funding gap for projects within LRA's research portfolio
- Accelerate the pace at which promising LRA-supported foundational research reaches clinical evaluation and ultimately transitions to a viable therapeutic or diagnostic development strategy

Utilize traditional grant-making apparatus in a non-traditional way to accelerate translation of LRA-funded projects

Translation Bridge Award – Features

- Previous LRA-funded projects
- Milestone-driven projects with clear objectives, well-defined on the translational path, with relatively near-term clinical potential
- Projects that aim to establish a robust data validation package, including pre-clinical or pilot clinical studies, to advance the proposed entity or product.
- Up to **$450,000** over two years (milestone based)
- Allow funding to and partnerships with start-ups and small biotech companies

Creating a “Bridge Plan”



- Therapeutic hypothesis
- Brief background and supporting data
- Is the foundational science fully validated?

- Scientific objectives
- Non-scientific objectives (legal, regulatory, business)
- Objectives should further the discovery towards a clinical evaluation

Point B: Project Objectives

- Need to be described from a translational or from a therapeutic / diagnostic development perspective:
  - What is needed to further the discovery towards a clinical evaluation?
  - Both scientific and non-scientific objectives

Examples of scientific objectives:

- Lead compound identification and optimization
- Phase 2/3 biomarker validation (on clinical specimen or a retroactive clinical evaluation)
- Scale up animal studies to power results

Examples of non-scientific objectives (legal, regulatory, business):

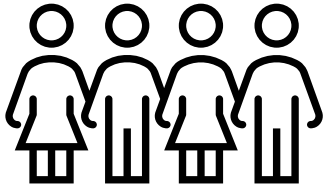
- Creating or strengthening an intellectual property position
- IND filing or initiation of a clinical trial
- Launching a commercial enterprise, such as a start-up company, around the entity or product or securing additional rounds of financial backing or funding
- Raising industry interest around the entity or product or forging a commercial partnership

Project Plan – Getting from Point A to Point B

- Sequential, dependent milestones with clear go/no go checkpoints
- Milestone is described as the endpoint (sub-objective)
  - Example: identifying and optimizing lead compounds to a validated target
    - Milestone 1: high throughput screen
    - Milestone 2: hit-to-lead screen
    - Milestone 3: lead compound/s optimization
- Experimental plan to reach each milestone – key set of experiments
- Budget and timeframe
- Project team:
  - Key personnel with relevant expertise
  - No trainees
  - CROs allowed

Review

Unique committee of industry reps, VCs, IP lawyers, clinicians and academics



- ✓ Strength of the therapeutic hypothesis and supporting data
- ✓ Strength, feasibility, and capacity of milestones to reach project objectives
- ✓ Strength of Go/no-Go checkpoints
- ✓ How close is project endpoints to clinical evaluation or clinical proof-of-principle?
- ✓ How far along is it on the clinical development path?

Post award and monitoring

- Comprehensive pre-activation activities including:
  - Changes to the project plan to align with reviewer comments
  - Changes to the milestones to create a viable plan
- Frequent and “hands on” monitoring, including consultation with external experts on progress
- More stringent funding scheme – funding dependent on go/no-go checkpoints, more aligned with industry and de-risks the investment

Experience with first cycle (2024)

- Robust response
- Applicant education
- Value of unique review panel (improved projects) – with a need for reviewer education and attention to conflicts of interest and confidentiality
- Positive feedback from community
- Diverse project portfolio

Thank you!

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