Rutgers iJOBS: Journey from a Pharmacology Ph.D. to Pharma Project Management

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Presented by: PMINJ Life Sciences LCI
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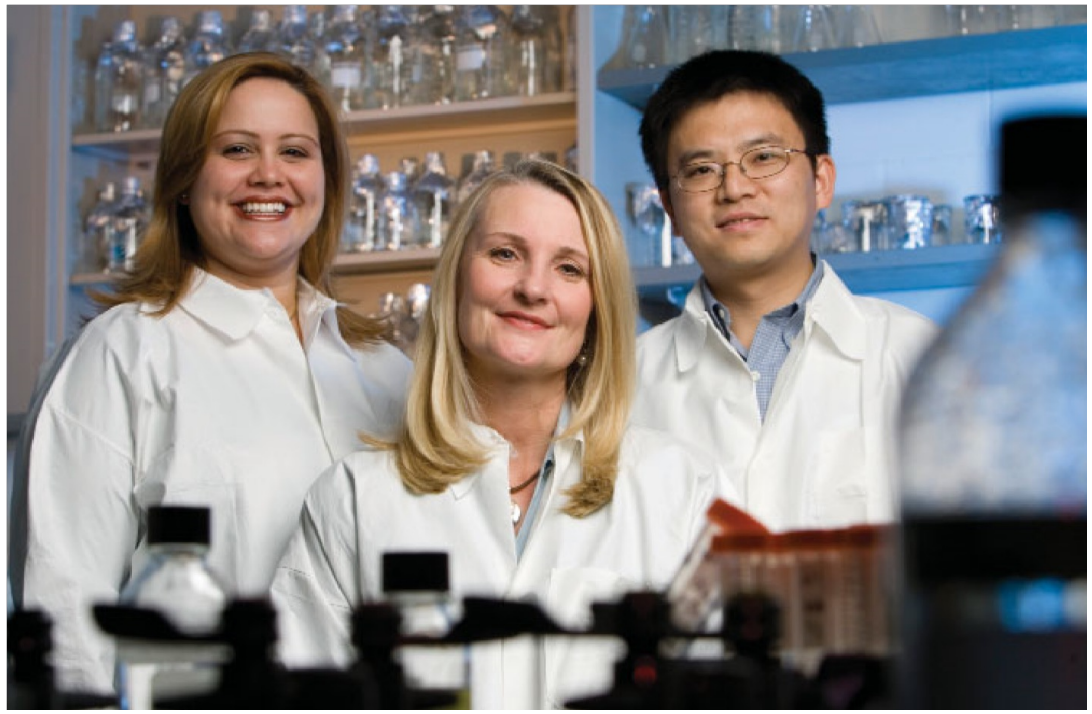
Career Journey

- **Ph.D. Cellular and Molecular Pharmacology** (2008)
  UMDNJ Graduate School of Biomedical Biosciences & Rutgers University

- **Awarded the New Jersey Commission for Science and Technology Post-Doctoral Fellowship:** The Commission on Science and Technology Post-Doctoral Fellowship pays the salary of competitive recent graduates to work in small New Jersey technology companies, providing companies with new talent and expertise. $150,000



Rebecca Baerga, Kathleen Scotto, and Thesis Advisor Shengkan (Victor) Jin

Career Journey

Director, Preclinical Operations at Niiki Pharma, Cancer biotech startup in Hoboken, NJ (2008-2012)

- Designed and executed preclinical anti-tumor experiments including PK/PD and determined mechanism of action. Arranged and oversaw study conduct through contract research organizations and independent academic institution investigators. Prepared in vitro and in vivo preclinical data (activities, budget, resources and timelines). Hired contract research organizations and academic collaborators and led implementation of preclinical studies required to support initiation of first in human studies. Recruited, trained and mentored associate project manager.
- Key Achievements:
  - Managed successful preclinical program allowing submission of two Investigational new drug applications to FDA.
  - Helped legal counsel identify unique concepts protected based on identified preclinical data and author and submit regular and provisional patent applications in various global locations.
  - Aided chief medical officer in ensuring proper clinical trial setup and execution within designated schedules and budgets.

Lead Research Project Manager at Educational Testing Service (ETS), Princeton, NJ (2012-2017)

- Reported to the Vice President of Research and was responsible for ensuring the advancement of ETS's Research Pipeline by overseeing work related to New Product Development.
- Key Achievements:
  - Directed launch of first Center for Academic and Workforce Readiness and Success product called SuccessNavigator, an online, non-proctored, self-assessment and development tool for incoming college students.
  - Directed all phases of WorkFORCE Product Suite and Trade Adjustment Assistance Community College and Career Training Grant Programs.

Career Journey

- **Director, Global Project & Alliance Management, Merck Research Laboratories**

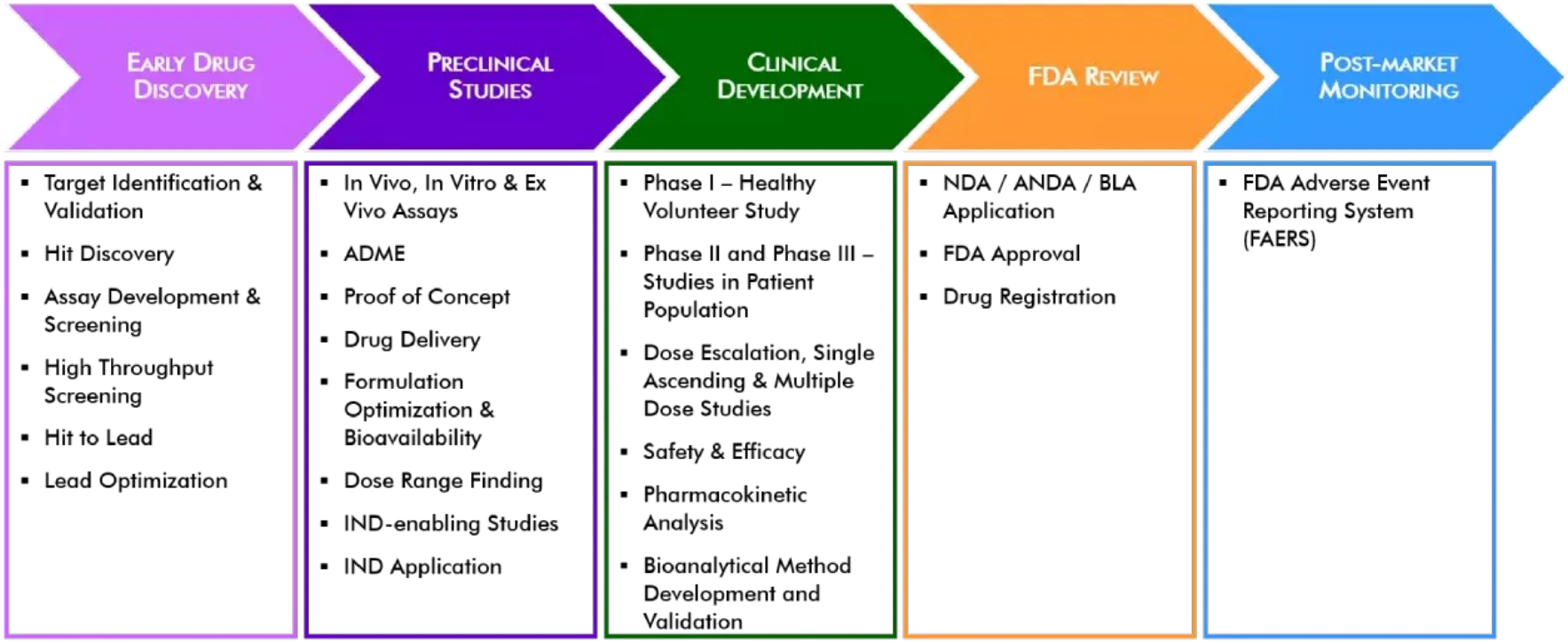
  Currently lead the HIV Treatment Product Development Team, Drug Development Expert, & Staff Manager

  - Lead multiple drug development teams in partnership with drug discovery and clinical leaders by independently managing critical deliverables for drug development across the early, late and post-licensure space in multiple therapeutic areas
  - Serve as Staff Manager for Project Managers:
    - Responsible for screening, identifying, interviewing and hiring
    - Assess staff performance and ensure proper development based on engaging key stakeholders and reviewing project work

It can take up to 15 years and $2.6 billion* to bring a drug from Discovery to Market

* Tufts Center for the Study of Drug Development

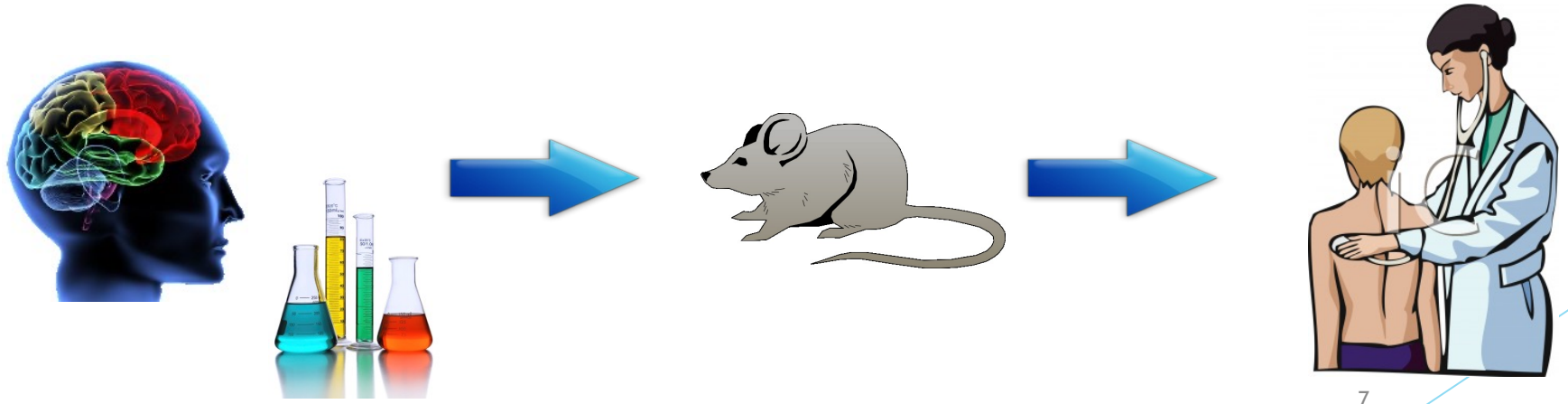
Drug Development Process



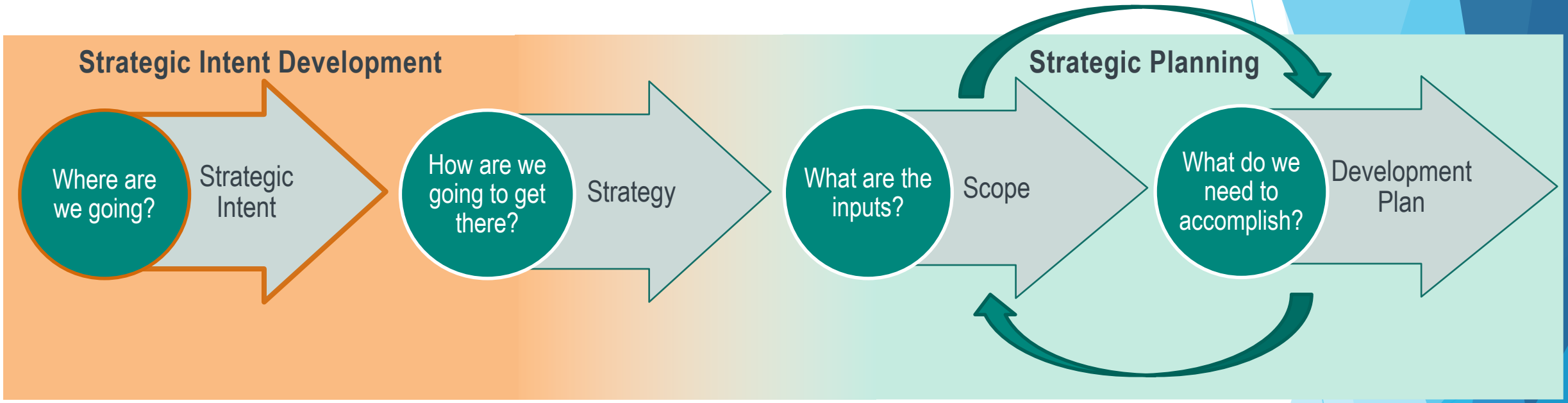
https://www.nebiolab.com/drug-discovery-and-development-process/

Discovery, Development, Approval, and Access

- Discovery
- Pre-Clinical (animal testing)
- Development (human testing)
- Approval (review by regulatory agencies)
- Access (Health technology assessment, formularies)
- Post-marketing development (new indications, formulations)



Focus on Strategic Intent, Strategy and Scope to drive the pipeline



The Strategic Intent must be in line with company's strategy and defines the means by which the team achieves its vision.

The Strategy breaks down the strategic intent into actionable approach for how to achieve the desired aspirations and goals.

Scope considers the full scope of work required to meet the strategic goal.

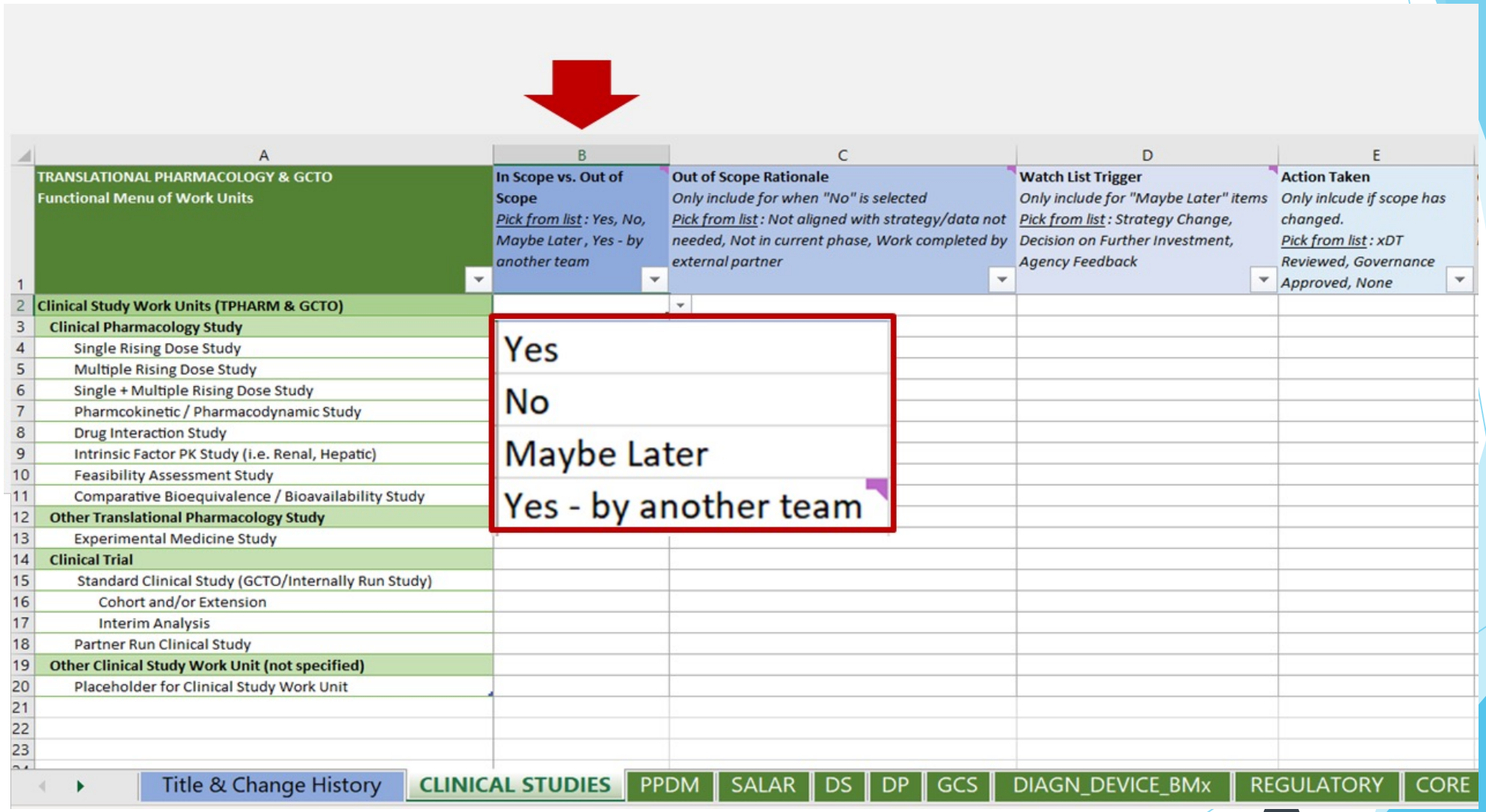
The development plan articulates key elements on what is needed to meet strategic intent and to complete the work.

Defining the Scope

As PMs, we define the scope by asking critical questions:

- What phase of development is your project currently in?
- What are the key objectives and goals for your project?
- What are the key milestones your project needs to achieve?
- What key governance decisions are required for your project?
- What key cross-functional activities/deliverables are required to meet the project objectives?
- What key cross-functional activities/deliverables are not required?
- What assumptions are true about your project?
- What constraints may define limitations on your project?

Scope Guidance – Example



	A	B	C	D	E
1	**TRANSLATIONAL PHARMACOLOGY & GCTO Functional Menu of Work Units**	**In Scope vs. Out of Scope** *Pick from list: Yes, No, Maybe Later, Yes - by another team*	**Out of Scope Rationale** *Only include for when "No" is selected* *Pick from list: Not aligned with strategy/data not needed, Not in current phase, Work completed by external partner*	**Watch List Trigger** *Only include for "Maybe Later" items* *Pick from list: Strategy Change, Decision on Further Investment, Agency Feedback*	**Action Taken** *Only inlcude if scope has changed.* *Pick from list: xDT Reviewed, Governance Approved, None*
2	**Clinical Study Work Units (TPHARM & GCTO)**				
3	**Clinical Pharmacology Study**				
4	Single Rising Dose Study				
5	Multiple Rising Dose Study				
6	Single + Multiple Rising Dose Study				
7	Pharmcokinetic / Pharmacodynamic Study				
8	Drug Interaction Study				
9	Intrinsic Factor PK Study (i.e. Renal, Hepatic)				
10	Feasibility Assessment Study				
11	Comparative Bioequivalence / Bioavailability Study				
12	**Other Translational Pharmacology Study**				
13	Experimental Medicine Study				
14	**Clinical Trial**				
15	Standard Clinical Study (GCTO/Internally Run Study)				
16	Cohort and/or Extension				
17	Interim Analysis				
18	Partner Run Clinical Study				
19	**Other Clinical Study Work Unit (not specified)**				
20	Placeholder for Clinical Study Work Unit				
21					
22					
23					

Yes
No
Maybe Later
Yes - by another team

Title & Change History | CLINICAL STUDIES | PPDM | SALAR | DS | DP | GCS | DIAGN_DEVICE_BMx | REGULATORY | CORE

Case Study

$32 PMI Student Membership
Includes Local Chapter for free
www.pmi.org/membership/student

Student Group Memberships:
www.pmi.org/membership/join/group/student

PMINJ website www.pminj.org
Life Sciences LCI

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Questions?