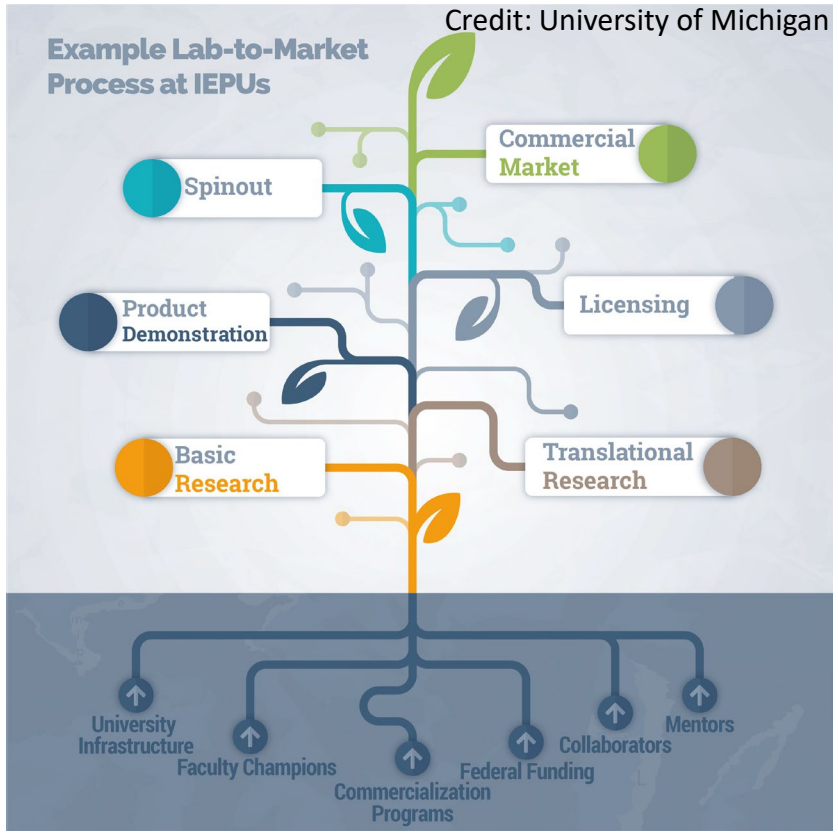

Credit: University of Michigan

CATALYZE
Accelerating Translation

From Research Aims to Actionable Milestones: Planning, Tracking, and De-Risking Your Project

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Who This Talk Is For

Early translational researchers

Teams transitioning from R01-style planning

Scientists new to product-oriented execution

Applicants preparing Catalyze-like submissions

Why This Matters

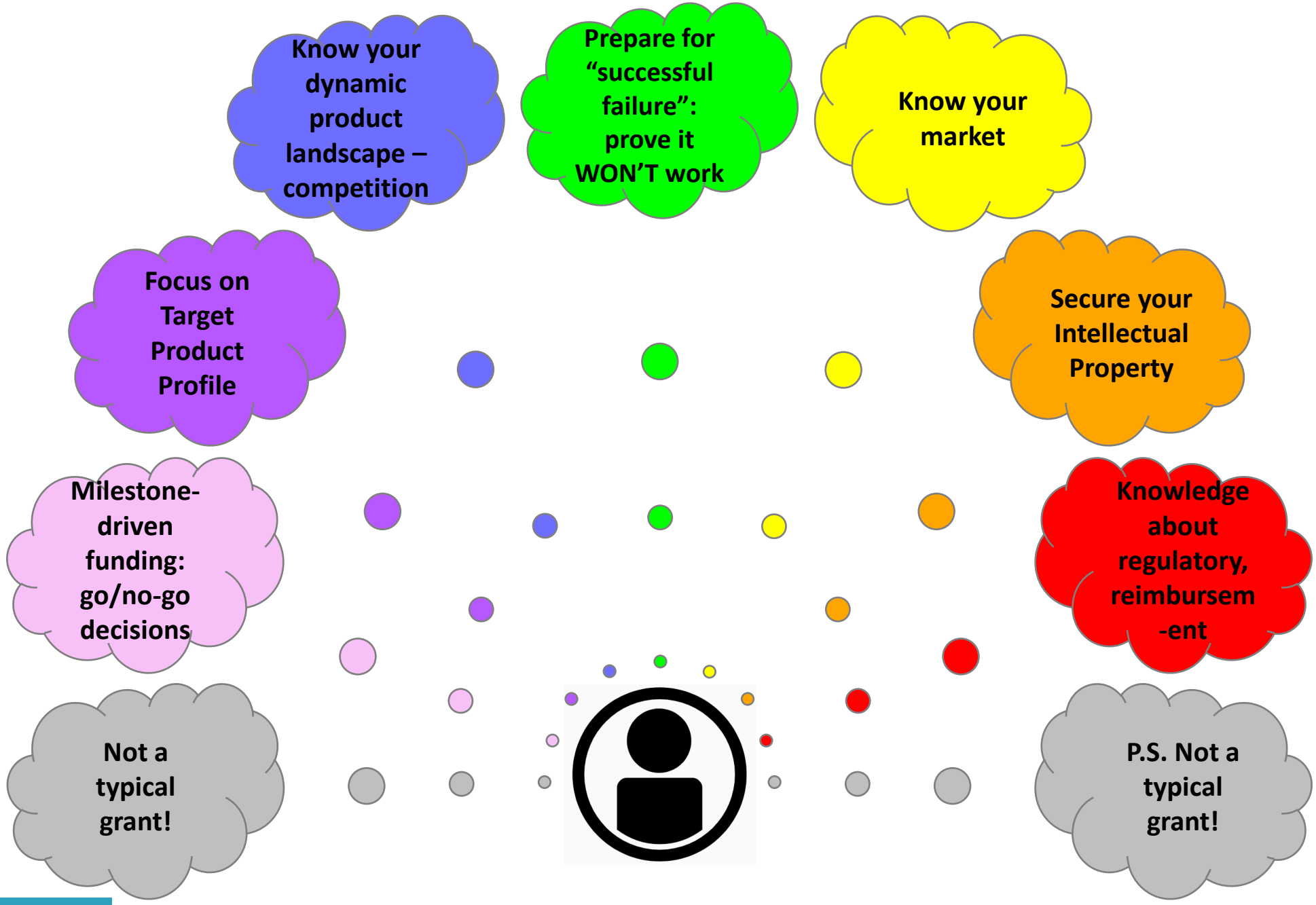
☒ Strong science alone doesn’t guarantee translation/impact

☒ Most projects stall due to planning gaps

☒ Late discovery of risks is expensive

☑ Milestones help surface risks early

☑ Project management connects science to outcomes


Know your dynamic product landscape – competition
Prepare for "successful failure": prove it WON'T work
Know your market
Focus on Target Product Profile
Secure your Intellectual Property
Milestone-driven funding: go/no-go decisions
Knowledge about regulatory, reimbursem-ent
Not a typical grant!
P.S. Not a typical grant!

The Core Shift: Research vs. Translation

- Research focuses on discovery and learning; translation focuses on readiness and decisions
- Research tolerates ambiguity; translation reduces it
- Milestones reflect this shift in thinking

Research Aim	Translational Milestone
Knowledge-driven (*what do we want to learn?)*	Risk-focused (*what must be proven?)*
Hypothesis-focused (*what do we want to learn?)*	Decision-driven (*requires clear outcomes*)
Open-ended (*tolerates partial answers)*	Binary-ish (*requires clear outcomes)*

What A Milestone Is/Is Not

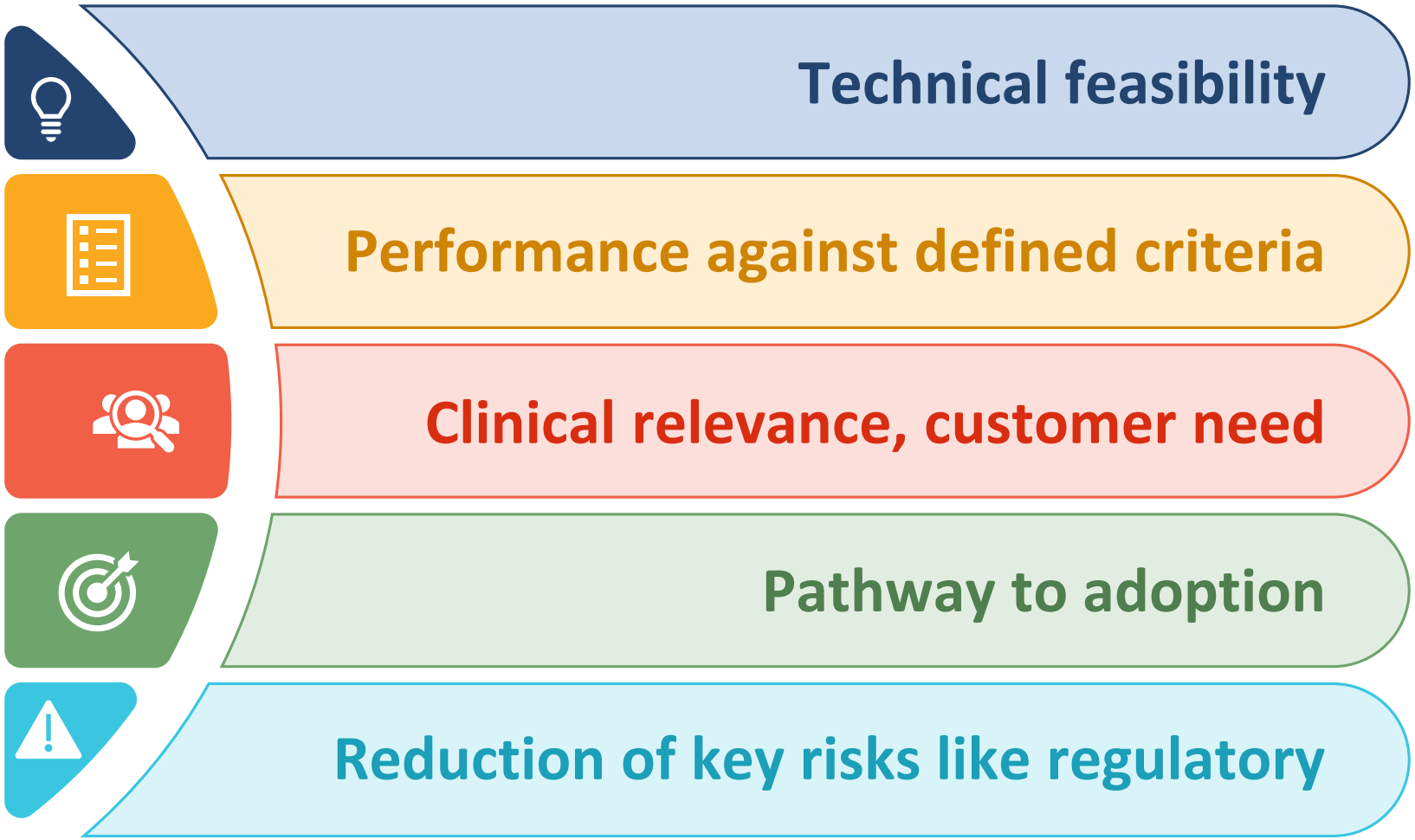
- A predefined checkpoint tied to evidence
- Designed to support a decision (go/no-go)
  - Focused on reducing uncertainty
- Measurable and time-bound
- Used to guide next steps

- A task list or workflow description
- A research aim rewritten
- “Complete experiment X”
  - Vague statements of progress
  - Success by effort alone

What Milestones Do

- Clarify whether progress is sufficient
- Enable prioritization and sequencing of work
- Reduce subjective decision-making by addressing key translational risks
- Support course correction
- Signal readiness to external stakeholders
- Support responsible use of resources

What Good Milestones Measure



Diagnostic Technology Example

A Blood Based Diagnostic Assay to Detect Early Pulmonary Vascular Remodeling in Patients at Risk for Pulmonary Hypertension (PH)	
Hypothesis-Driven Research Aim: *Circulating biomarker X correlates with early pulmonary vascular remodeling in animal models and human samples*	**Translational Objective:** *Determine whether biomarker X can be developed into a viable early-stage diagnostic for PH*
Characteristics • Focused on **biological insight** • Open-ended scope • Success defined by **statistical significance** • Generates new questions rather than decisions	**Milestone 1: Analytical & Clinical Feasibility** **Deliverables (Defined):** • Develop and **lock a prototype assay** • Demonstrate: Sensitivity ≥ **85%**, Specificity ≥ **80%**, Coefficient of variation (CV) ≤ **15%** • Evaluate performance in: ≥ **50 archived patient samples**, Pre-defined intended-use population • **Timeline:** 6 months
Typical Outcomes • Publications • Follow-on hypotheses • Additional grant proposals	**Go/No-Go Decision** • **GO if:** All performance thresholds are met, Reproducibility is demonstrated, Preliminary differentiation from standard of care is plausible • **NO-GO/PIVOT if:** Performance falls below thresholds, Variability is too high, Clinical utility remains unclear

Side-by-Side Comparison

Dimension	Hypothesis-Driven Aim	Translational Milestone
Primary Question	“Is this interesting?”	“Is this viable?”
Outcome	Knowledge	Decision
Metrics	p-values	Sensitivity, specificity, CV
Timeline	Open-ended	Fixed
Success	Interpretation-based	Threshold-based
Consequence	More research	Go/No-Go

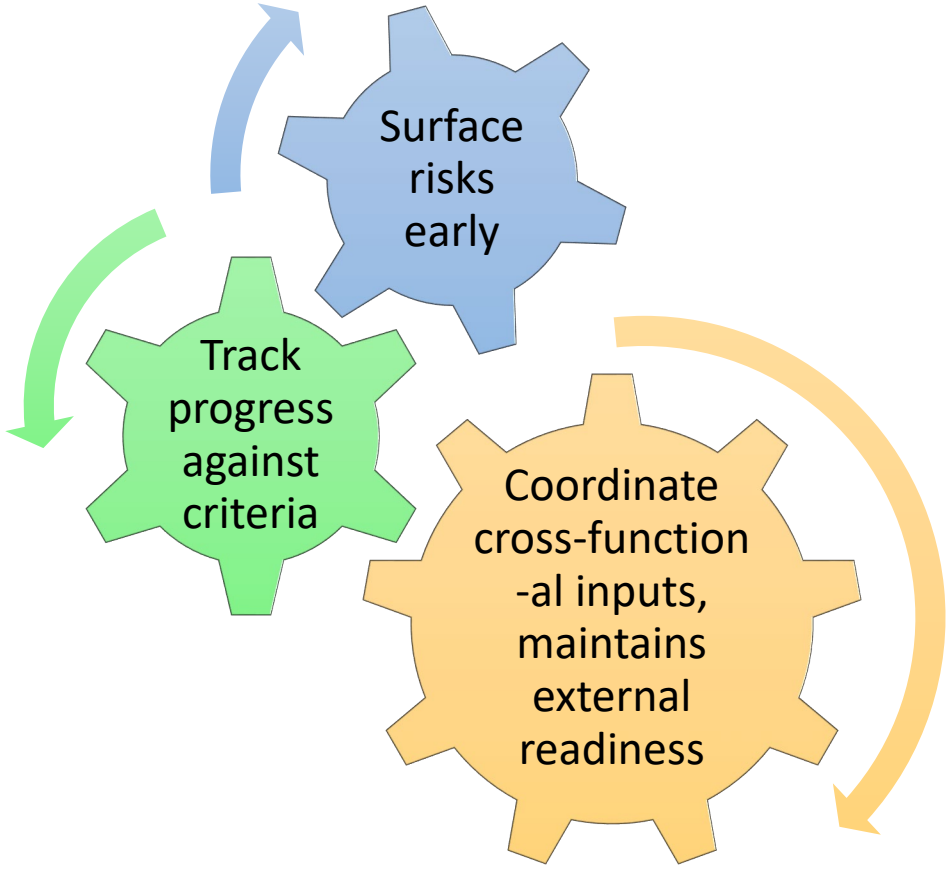
Strong translational proposals don’t just propose experiments.
They propose *decisions that reduce risk*.

Why Milestones Enable Project Management

- Make ambiguity explicit by surfacing assumptions
- Tie progress to evidence, not activity
- Enable early identification of technical, regulatory, and adoption risks
- Allow progress to be tracked objectively over time
- Create structured go/no-go decision points
- Allow replanning when assumptions fail

Who Is A Project Manager? What Do They Do?

- Not just an administrator/scheduler
- Often a scientist/founder
- Accountable for alignment across contributors, not final decisions
- Brings an independent, risk-focused lens
- Helps keep momentum without losing rigor



External Interfaces PMs May Track

- Regulatory pathways (e.g., FDA expectations)
- IP and TTO/innovation ecosystem Integration
- Reimbursement considerations
- Adoption logic
- Manufacturing/scalability considerations
- Stakeholder expectations and timelines

How A PM May Work With A Team

Works with the PI and team to define and track clear, testable milestones

Helps identify and track key risks across science, regulatory, IP, and adoption pathways

Keeps the project aligned with funder expectations and external requirements

Facilitates evidence-based decisions at milestone checkpoints (advance, pivot, pause)

Acts as a neutral, independent lens – asking hard questions and identifying issues early

Common Applicant Pitfalls

- Milestones that describe effort, not evidence
- Success criteria that are vague
- Treating milestones as formalities
- Ignoring non-technical and product-development risks
- Not anticipating likely failures or troubleshooting paths
- Mistaking familiarity for evidence

Better Milestone Design Questions

- What assumption does this test?
- What risk does this reduce?
- What does success look like, concretely?
- What happens if it fails?
- Who cares about this result?

Setting Realistic Milestones & Tracking Progress

 Balance ambition with feasibility

 Define success criteria upfront

 Track progress against evidence, not effort

 Use regular check-ins to assess status

 Adjust plans before issues compound

Anticipating Challenges, Using Go/No-Go Decisions

Be prepared to identify and address research translation risks early:

- Watching for warning signs (missed criteria, shifting goals)
- Using milestones as formal decision points
- Pivoting when evidence suggests a better path
- Stopping early can be a success

Example: Weak vs. Strong Milestone (Therapeutic)

Weak Milestone: *Demonstrate efficacy of the therapeutic in a preclinical model*	**Stronger Milestone:** *Demonstrate that the therapeutic achieves a ≥25% improvement in cardiac function compared to standard of care in a validated large animal heart failure model, with no dose-limiting toxicity observed over 28 days*
Why this is weak • Vague success criteria (what level of efficacy?) • No indication of model relevance to human disease • Doesn't enable a clear decision • Could be interpreted as partial success	**Why this is strong** • Defines what success looks like quantitatively • Uses a clinically relevant model • Addresses both efficacy and safety risk • Enables a clear go/no-go decision for further development

What Reviewers Often Want To See

- ☑ Clear linkage between milestones and key product development risks
- ☑ Objective, measurable success criteria
- ☑ A realistic plan that enables a go/no-go decision
- ☑ Awareness of regulatory, IP, reimbursement, market, and adoption context
- ☑ Willingness to make evidence-based decisions

R01 Thinking vs. Catalyze Thinking

- Knowledge generation → Risk mitigation
- Long-term exploration → Staged decisions
- PI/Lab-centric work → Stakeholder-based accountability
- Flexibility → Structured progress
- Curiosity → Readiness

If You're Considering A PM Role

You don't need "PM" in your title – many start as scientists wearing multiple hats

Strong PMs are curious, organized, and comfortable asking hard questions

Requires thinking beyond the bench: regulatory, IP, reimbursement, adoption

Success means enabling decisions, not owning all the answers

Learn to separate what's interesting from what's necessary to move forward

Leveraging Catalyze Support

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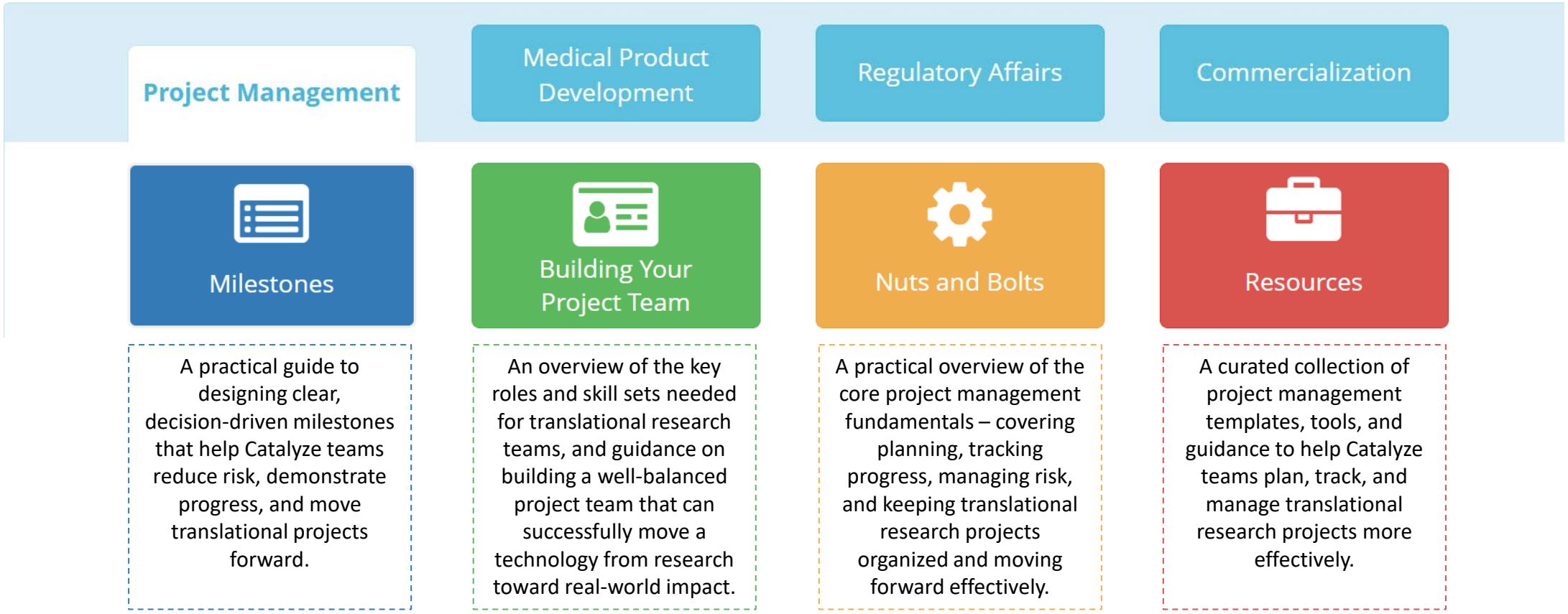
[Catalyze Project Management Resources]

Project Management Resources



Key Takeaways

1. Milestones drive decisions – not just progress
2. Realistic planning sustains momentum
3. Project management reduces surprise and risk
4. Evidence should guide pivots and stops
5. Strong execution accelerates impact

It Takes A Village To Raise A Business

Source: LinkedIn

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IT TAKES A VILLAGE TO BUILD A BUSINESS – AND PROJECT MANAGEMENT IS HOW THAT VILLAGE WORKS TOGETHER TO DELIVER RESULTS!