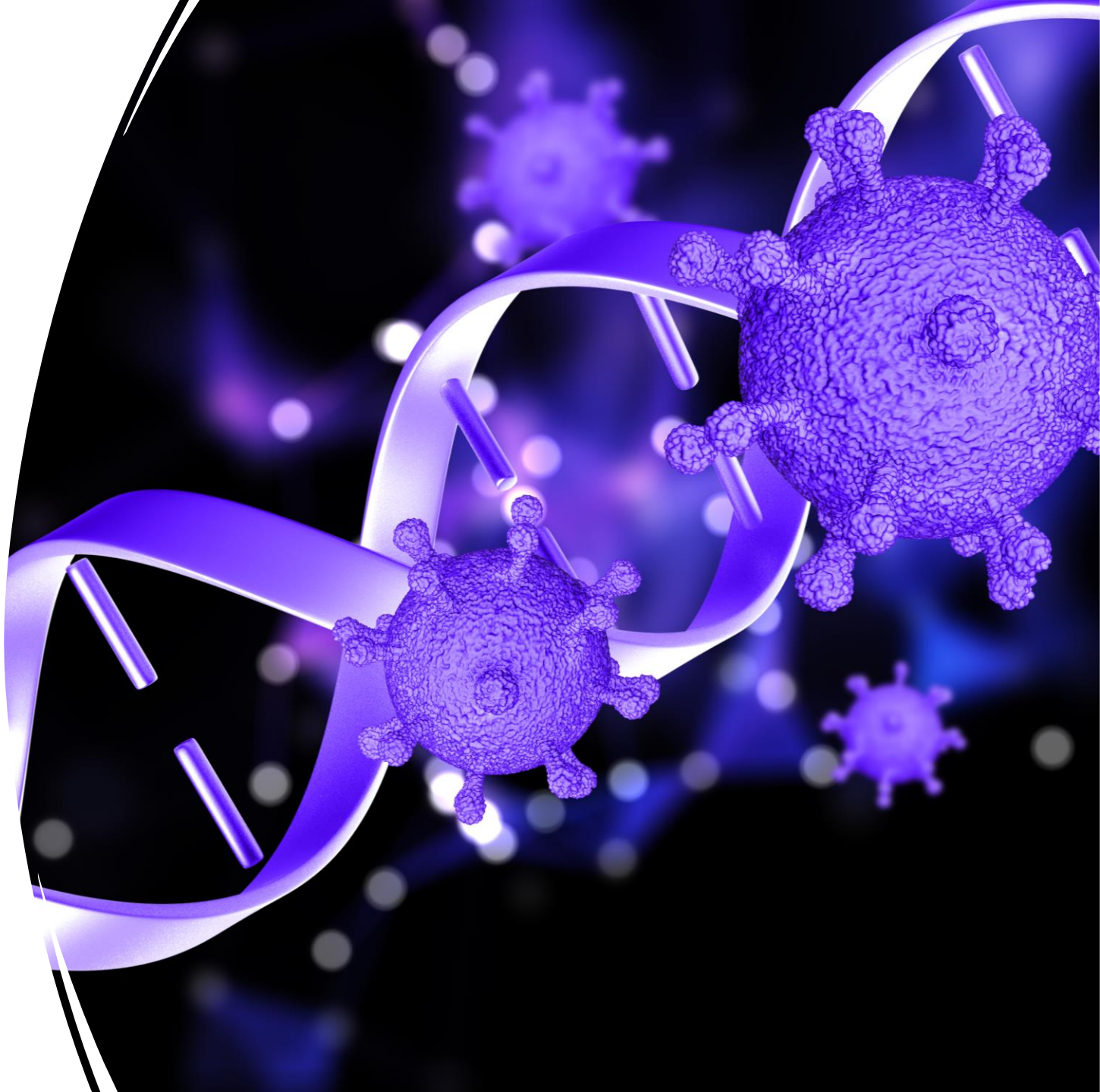
Work Portfolio



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Disclaimer

The data shown are examples of our past work, using the hypothetical product name "S01" and without disclosing confidential client information. Each piece represents a different project, so no consistency is expected between slides.

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Dashboard

Project Title: Clinical Development of S01 as a Novel Therapy for Solid Tumors

Project Goal: IND enabling study using S01 to treat Solid Tumors

Key Achievement and upcoming Milestones:
Overall Status: On track

Function	Task	Completion Percentage	Last Milestone Status	Overdue Tasks	Due Date	Owner	Risk
Non-Clinical	1. 12w DRF Rodent and NHP 2. 12w GLP Rodent and NHP	1. 100% 2. 40%	Achieved	None	3/1/2025	Steve	
Clin Dev	1. Study design and protocol development	1. 50%	Achieved	None	4/1/2025	Raj	
Clin Ops	1. Site identification 2. Site selection	1. 100% 2. 40%	Achieved	None	4/1/2025	David	
CMC	1. Tox batch manufacture 2. Analytical assay development	1. 100% 2. 60%	Achieved	None	5/5/2025	Stacy	
Regulatory	1. Medical writing timeline	1. 30%	Achieved	None	3/1/2025	Ana	

- **Overall Status -** Displays project status; shows whether your projects are on track, off track, on hold, or at risk
- **Completion Percentage** - Project progress in percentage completed. Monitors project in real-time
- **Last Milestone Status** - Displays last milestone the project has achieved. Helps accurately track project in its life cycle
- **Overdue Tasks** - Shows the number of overdue or incomplete tasks in different projects
- **Due Date** - Displays project's due date, predicted completion date, and deviance
- **Owner** - Shows the team members responsible for various projects
- **Risk** – Anticipated risk level indicated by color code; Red (high), Yellow (medium), Green (low)

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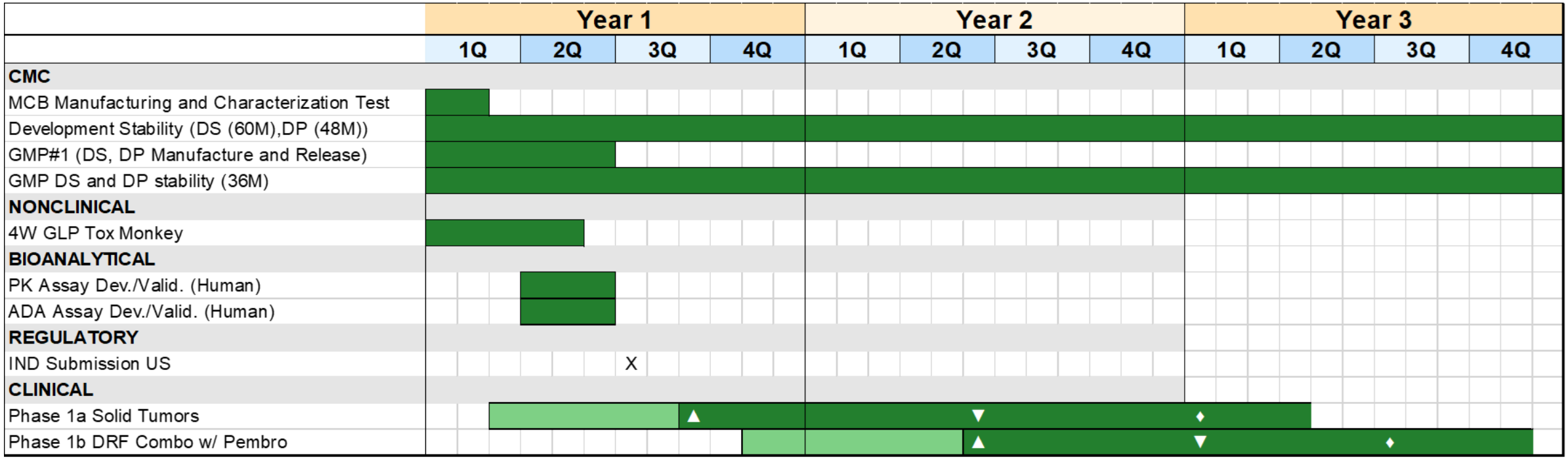
S01 Clinical Development: Green bar Timeline

A Green bar Timeline adapted from an Integrated Timeline Developed in MS Project and Smartsheet



Start Up | Activity | ▲ FPI | ▼ LPI | ◆ DATA

x: designates timing of event

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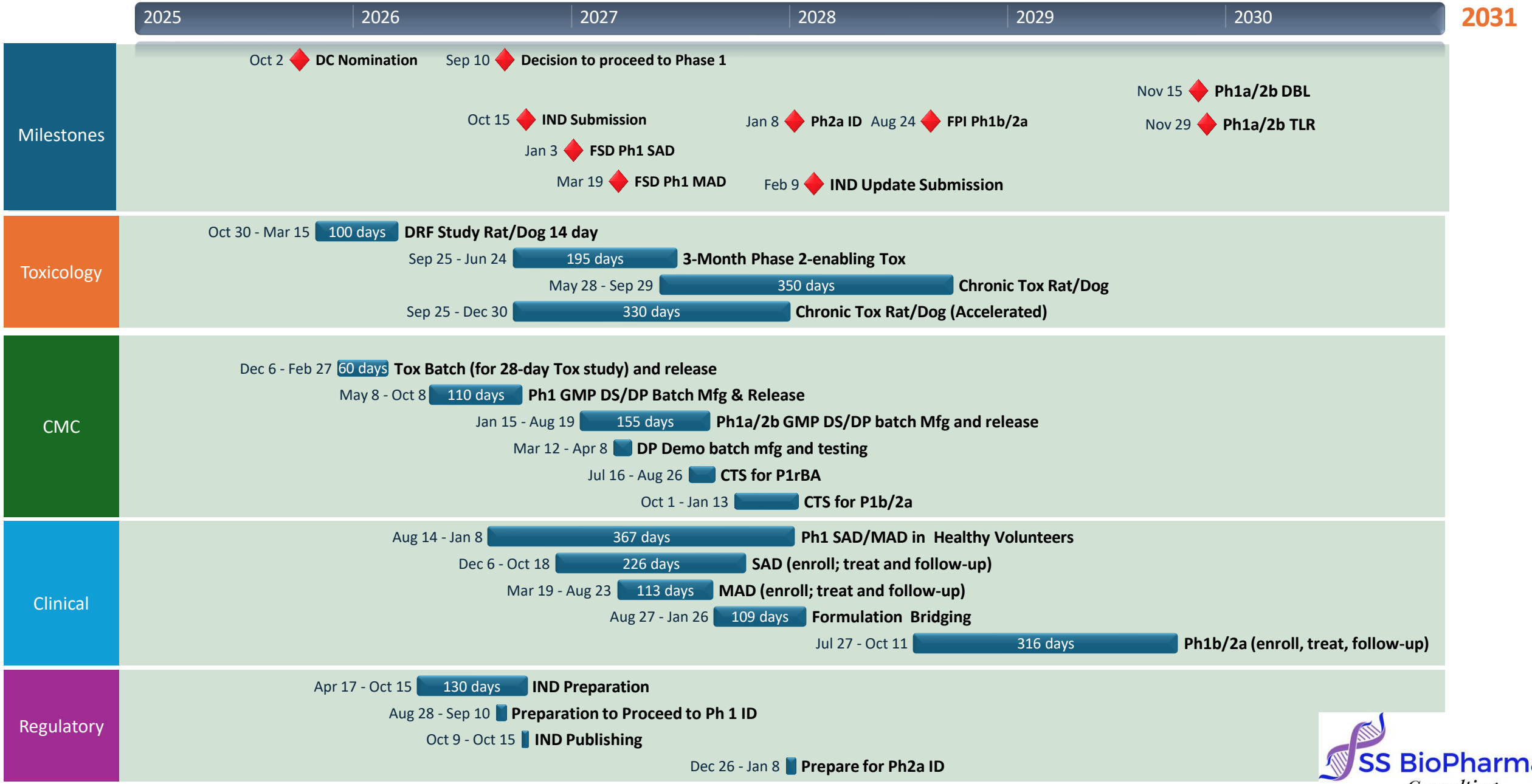
S01 Clinical Development: Swimlane Timeline



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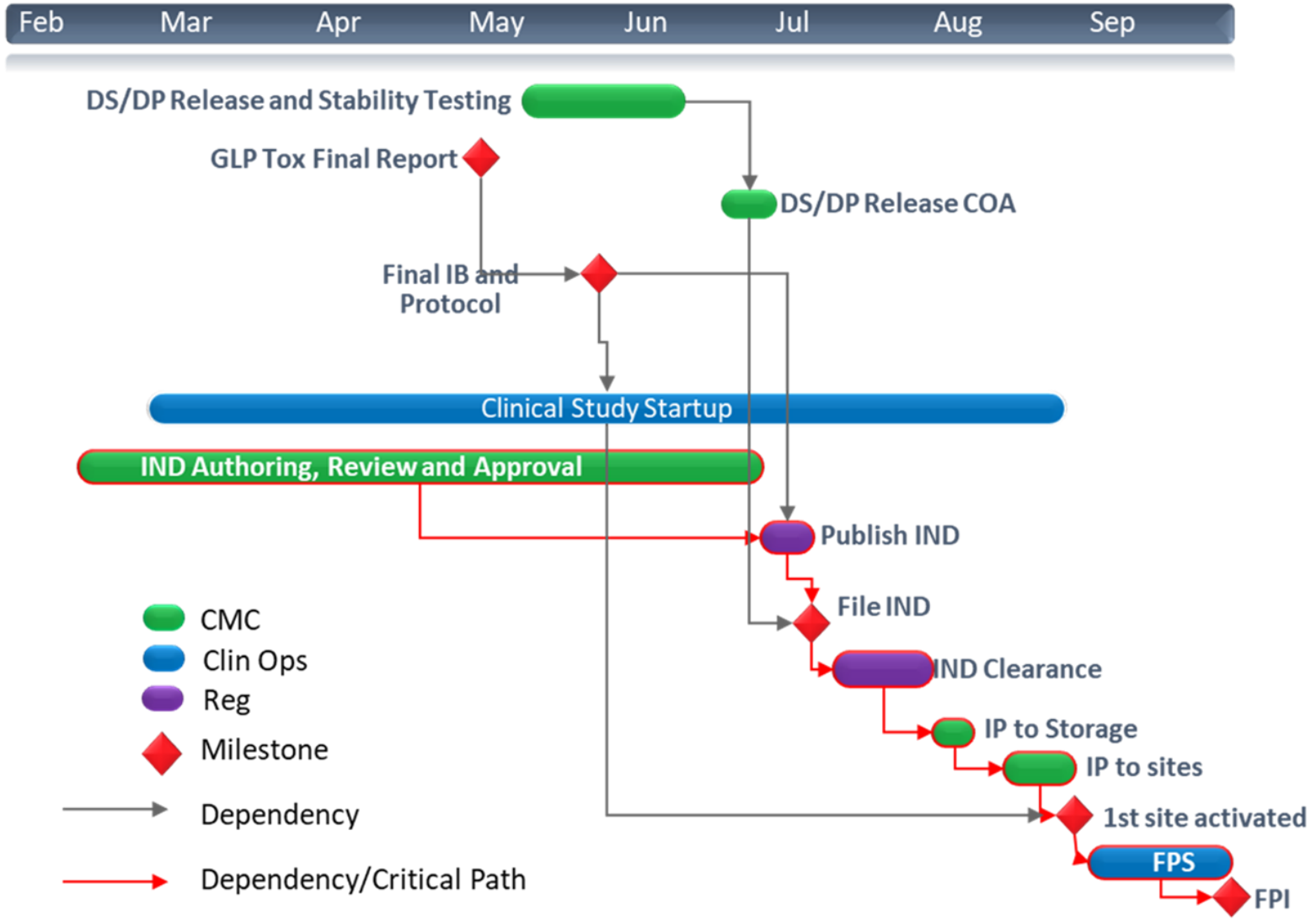
S01 IND submission and First Patient-in Timeline with Critical Path

Office Timeline with Critical Path and Milestone, adapted from an Integrated Timeline Developed in MS Project and Smartsheet



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S01 Budget
A. Summary; B. By Function and Phase

Assumption: SAD/MAD with sub-studies (n=152); Ph2 (n=120) 3y plus 1 y optional

A

	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Pre-IND	$ 858,500	$1,462,740								$2,321,240
Ph1	$ 240,000	$7,015,720	$3,995,000	$35,000						$11,285,720
Ph2		$1,677,800	$5,065,490	$6,994,990	$5,839,840	$5,230,000	$3,200,000	$3,200,000	$3,200,000	$34,408,120
Labor	$650,000	$4,175,000	$4,750,000	$5,850,000	$6,050,000	$6,250,000	$5,200,000	$6,025,000	$6,575,000	$45,525,000
Total	$1,748,500	$14,331,260	$13,810,490	$12,879,990	$11,889,840	$11,480,000	$8,400,000	$9,225,000	$9,775,000	$93,540,080

B

Study	Tox	CMC	Clin Pharm	BA	Clin Ops	Reg	Total
Pre-IND	$1,350,000	$547,000	$125,000	$364,240		$35,000	$ 2,421,240
Phase 1	$3,600,000	$2,235,000	$430,500	$935,220	$7,900,000	$10,000	$ 15,110,720
Phase 2		$10,210,000	$150,000	$1,023,120	$19,100,000		$ 30,483,120
Total	$4,950,000	$12,992,000	$705,500	$2,322,580	$27,000,000	$45,000	$48,015,080

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S01 Budget
C. By Function and Year

Assumption: SAD/MAD with sub-studies (n=152); Ph2 (n=120)

C

Study	2025	2026	2027	2028	2029	2030	2031	2032	2033	Total
Toxicology	$250,000	$2,900,000	$1,800,000	$0	$0					$ 4,950,000
CMC	$692,000	$2,020,000	$2,205,000	$4,085,000	$1,960,000	$2,030,000				$12,992,000
Bioanalytical	$144,000	$1,370,760	$590,490	$162,490	$54,840					$ 2,322,580
Clin Pharm	$12,500	$230,500	$245,000	$142,500	$75,000					$ 705,500
Clin Ops	$0	$3,950,000	$3,950,000	$2,550,000	$3,750,000	$3,200,000	$3,200,000	$3,200,000	$3,200,000	$27,000,000
Regulatory	$0	$35,000	$10,000	$0	$0					$ 45,000
Labor	$650,000	$4,175,000	$4,750,000	$5,850,000	$6,050,000	$6,250,000	$5,200,000	$6,025,000	$6,575,000	$45,525,000
Total	$1,748,500	$14,681,260	$13,550,490	$12,789,990	$11,889,840	$11,480,000	$8,400,000	$9,225,000	$9,775,000	$93,540,080
FTE	2.60	16.70	19.00	23.40	24.20	25.00	20.80	24.10	26.30	

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Risk Management Plan

	Identified Risk	Risk Rating	Mitigation Plan
BA	Anti Drug Antibodies (ADA) detected		Evaluating ADA impact on PK, efficacy and safety, and determine if ADA is correlated with AEs.
Clinical Dev	Ph2 subjects enrolled are not balanced or lesions are not consistent with assumptions; Stats assumptions may not hold		Review baseline characteristics to ensure lesions enrolled are within the expected range. Biostats to update assumptions based on BSLN characteristics enrolled
	Unexplained safety events (vision loss, inflammation, etc) trigger DSMB concern		Monitoring BCVA fluctuations with alerts and monthly patient profiles; requesting additional imaging when observed; reviewing safety listings on monthly basis; review cases with DSMB as needed
Clinical Operation	Study staff turnover due to Covid causes increase in data entry errors and greater protocol deviations		Close monitoring and retraining sites with staff turnover
	Subject dropout higher than anticipated (10% at 1-yr)		Closely monitor subject drop-out; discuss with sites the importance of enrolling patients committed to 1 y study; consider over enrolling up to 10%; rerun stats assumptions
	Lack of timely on-site source monitoring by the CRO results higher than expected protocol deviations (Covid related lack of travel/onsite visits)		Ensure the CRO monitors get SDV% up as quickly and possible and visit sites in person as soon as able
	Non-enrolling sites lead to resource drain		Cost and resource strain to maintain non-enrolling sites; proactive engagement with site from Client/CRO; warning letters will be sent on a case-by-case basis; site closures when needed
	Accelerated Ph2 enrollment puts drug supply on critical path for Ph3 FPI; Ph3 FPI timelines may be impacted.		Alliance partner anticipated Ph3 FPI timelines may be slower than Client assumptions so risk may be mitigated; understanding how Alliance partner Ph3 timelines are adjusted would help assess true risk

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Risk Rating  High  Critical

Key Performance Index (KPI)

Table shows KPIs used with target values for outsourced CMC QC and life cycle management projects.

KPI	Target
ARID (Average Review Iterations per Deliverable)	≤ 1.3
DRE (Defect Removal Efficiency)	≥ 90%
SOW (Statement of Work) completion	85% ≤ 5 days
Documents Review Process (from uploading of the document-1st time to approval)	≤ 20 days
Incidents/Deviation	≤ 2 per method
First Time Right-Stability Testing	≥ 95%

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Key Performance Index (KPI)

Table shows KPIs for a clinical trial

KPI	Target
From "open for enrollment" to "enrollment quota met"	TBD
Cost per enrolled subject	TBD
From IRB submit to IRB approval	TBD
Trial retention statistics	TBD

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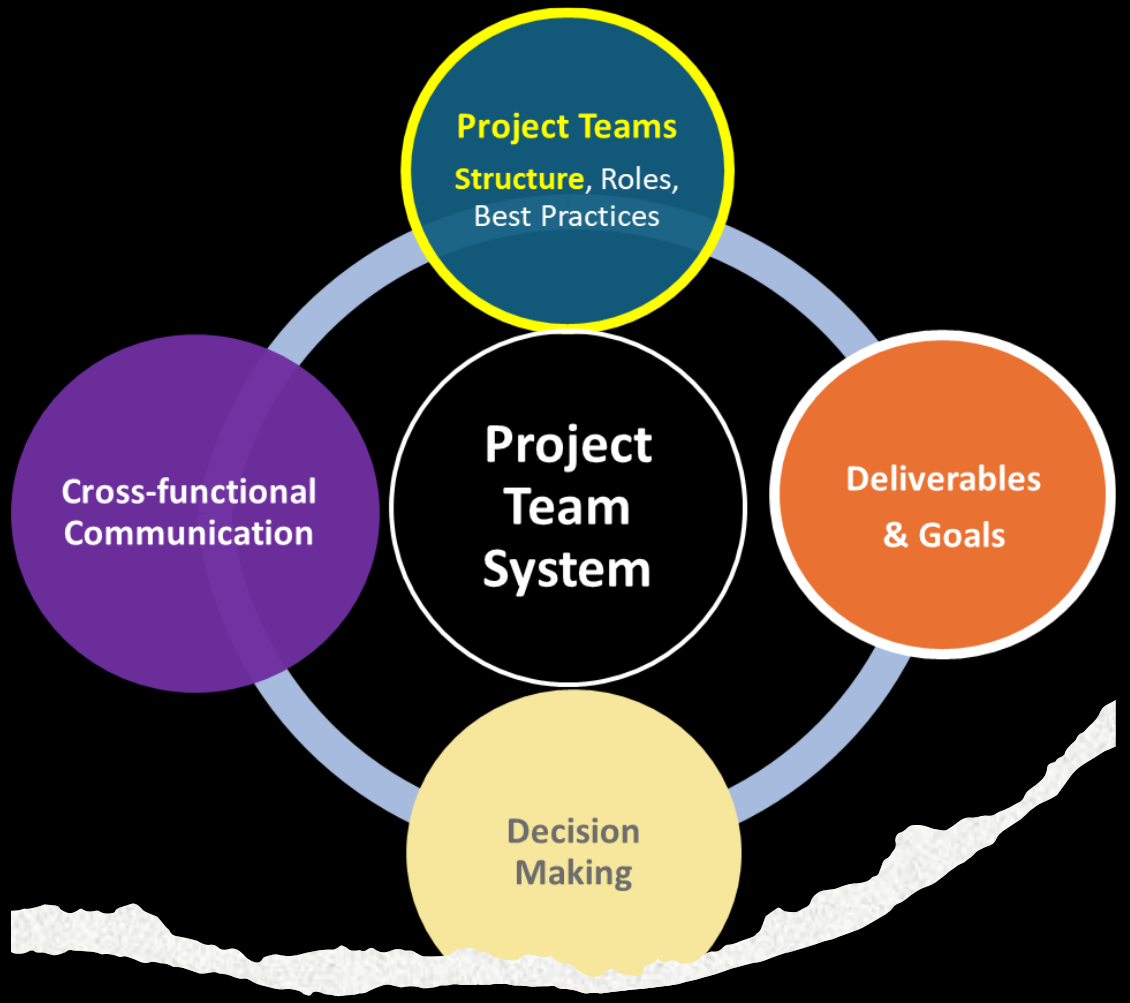
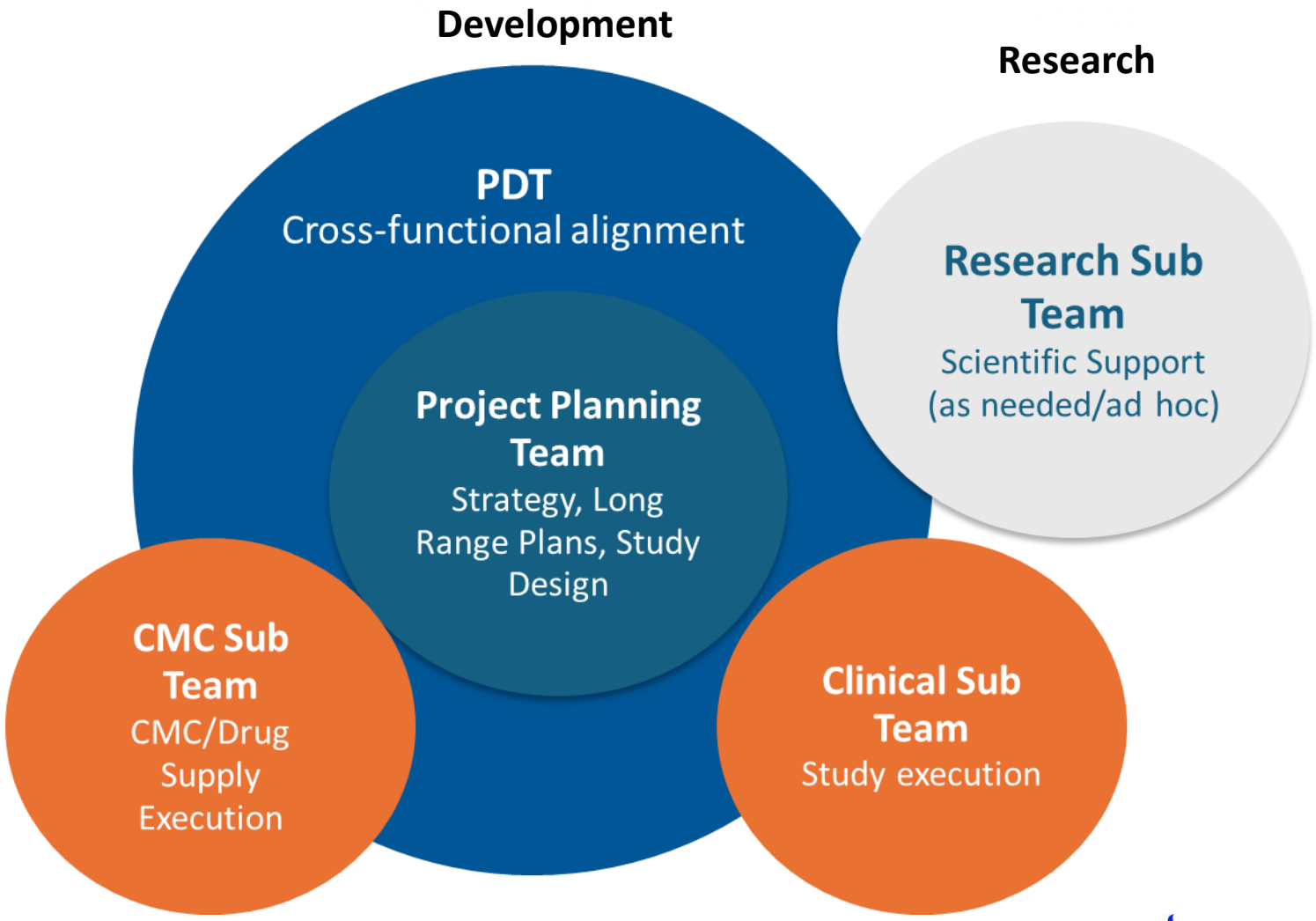
Project Management Office

Project Team System Key Components



Project Management Office

Project Team Structure



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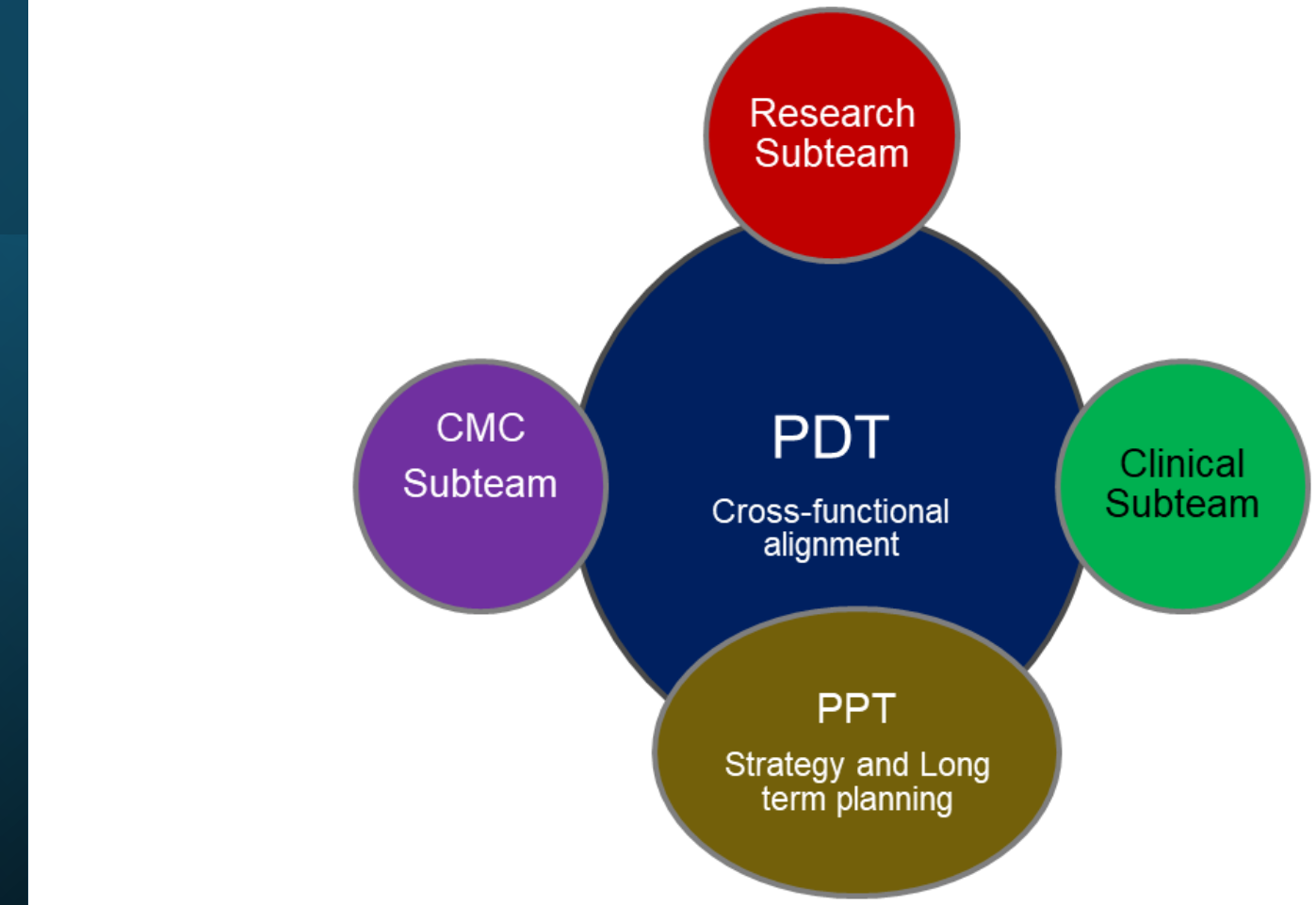
Project Management Office

Project Team Structure



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