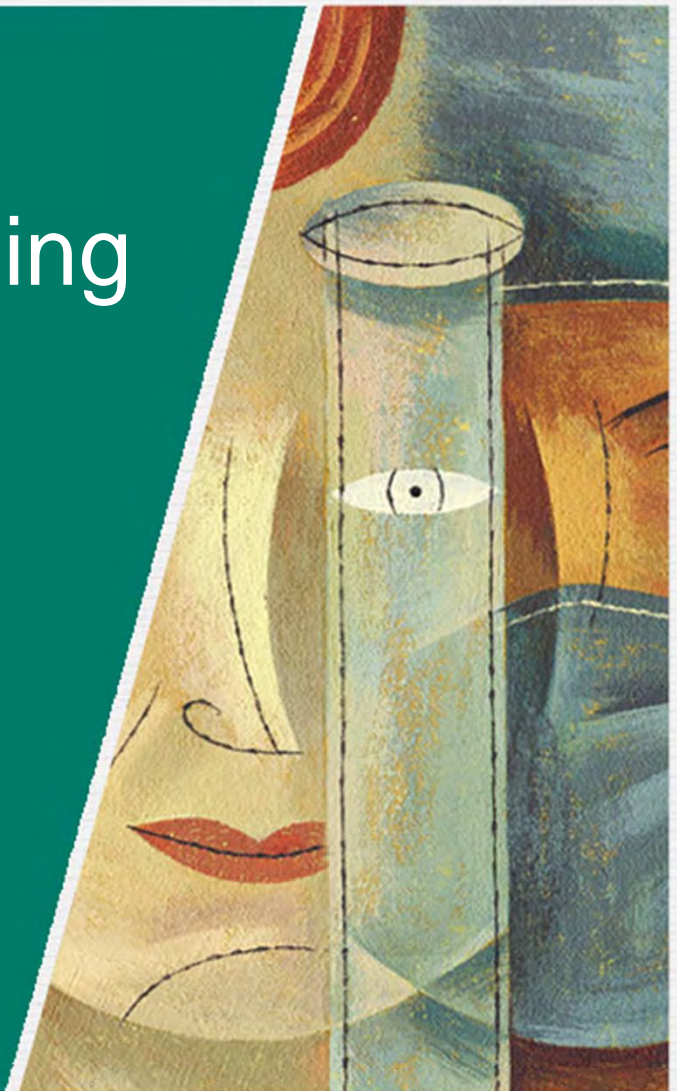


When, How and Why: Optimizing Resource Planning to Get the Most from Your Existing Resources

Todd Reul

Director, Clinical Services
ClearTrial LLC.



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Resource Management

Wikipedia

- The efficient and effective deployment for an organization's resources when they are needed
- Resource management is a key element to **activity resource estimating** and **project human resource management**. Both are essential components of a comprehensive project management plan to execute and monitor a project successfully.



The Operational Why

- Ensure effective utilization of resources
- Enable key business decisions proactively
 - To many resources
 - To few resources

Accomplish business goals in as **efficient**, **effective** and **appropriate** manner as possible!



The Financial Why



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Resource Management



1. Resource Planning
2. Portfolio Mgt
3. Tracking Progress
4. Reforecasting



Resource Planning

- Analysis/Projection of an individual project's resource demand
 - How?



Hopefully
Not!



Activity Based Costing

- Begins by deriving the level of effort for a specific resource to perform a given activity.
- After calculating the effort, one can derive costs for that specific task by factoring in the cost of the resource(s) who perform the activity.



Portfolio Management

- The process of managing several related projects, often with the intention of improving an organization's performance.

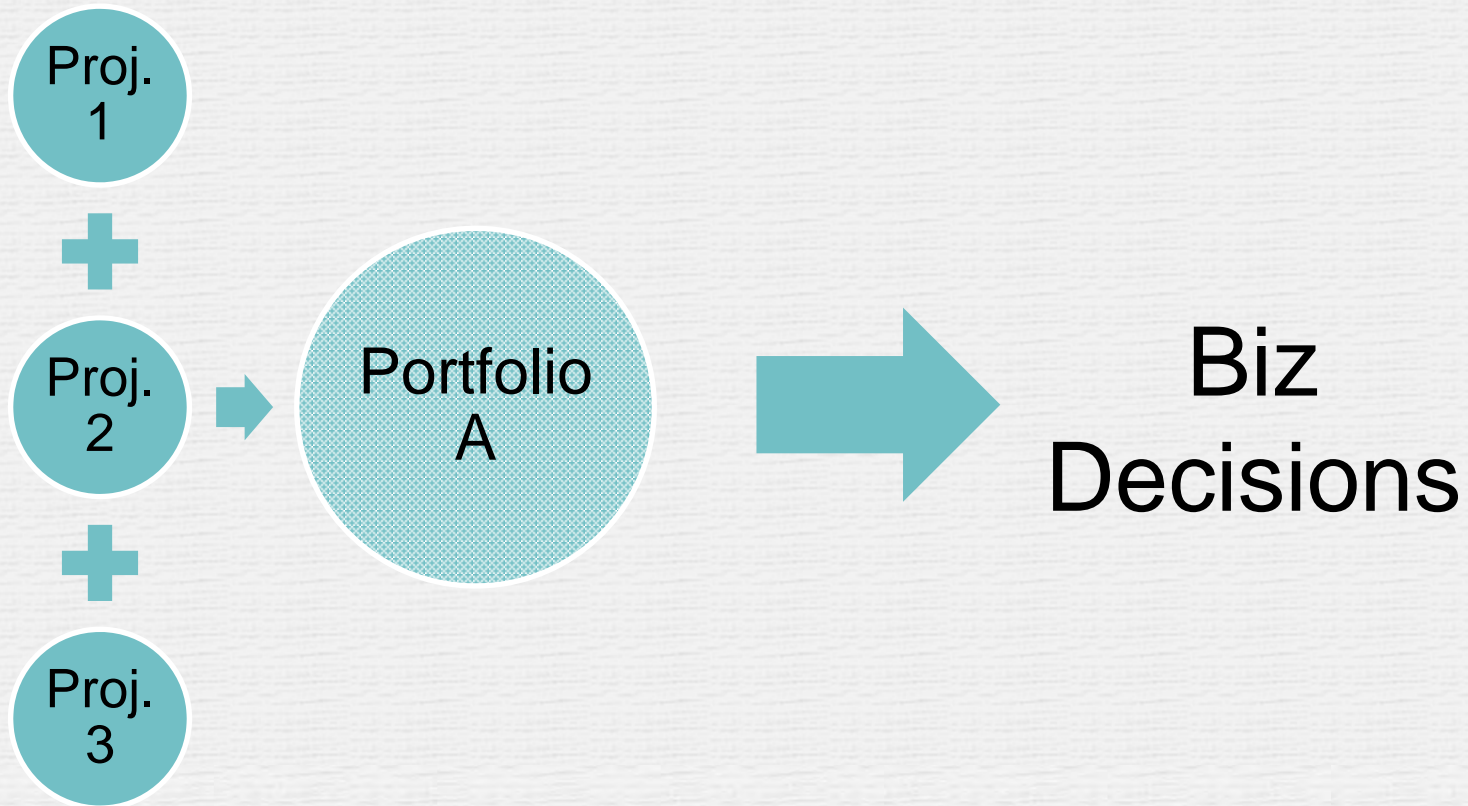


Portfolio Management

- Product/Compound
- Therapeutic Area
- Indication
- Geographic Region
- Department/Team
- Service Provider



Activity Resource Estimating Vs. Project Human Resource Management



Resource Demand

Named Resources



Tracking Study Progress

- If nothing ever changed...



Tracking Study Progress

- Multiple techniques and systems
- Informational vs. Actionable data
 - # investigative sites approved
 - # subjects enrolled

What does it mean to the project/business?



Earned Value Management

- PM technique for measuring project performance and progress in an objective manner
- Combines scope, schedule, and cost in a single integrated system
- Recent research have shown that the principles of EVM are positive predictors of project success¹

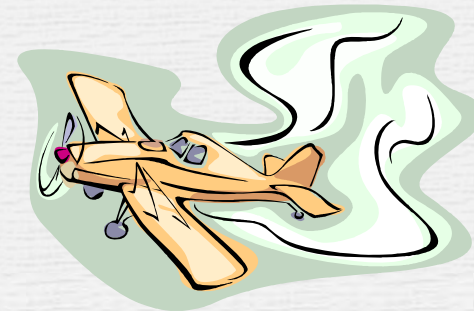
1: Marshall, Robert. *The Contribution of Earned Value Management to Project Success of Contracted Efforts*. Journal of Contract Management, 2007, pp. 21-331.



Reforecasting

- Applying actual data or assumption changes to the budget and/or resource planning projections on a regular basis.

Keeping things current!



Resource Management



1. Resource Planning
2. Portfolio Mgt
3. Tracking Progress
4. Reforecasting



Outsourcing

- Augments your current resources
- Sponsor and Service Provider partnership



Panelists

- Mid-size Pharma
- Major Service Provider
- Small Biotech

Questions?



When, How and Why: Optimizing Resource Planning to Get the Most from Your Existing Resources

Graeme Currie PhD

Head, Clinical Project
Management and Operations
Regeneron Pharmaceuticals Inc.

REGENERON



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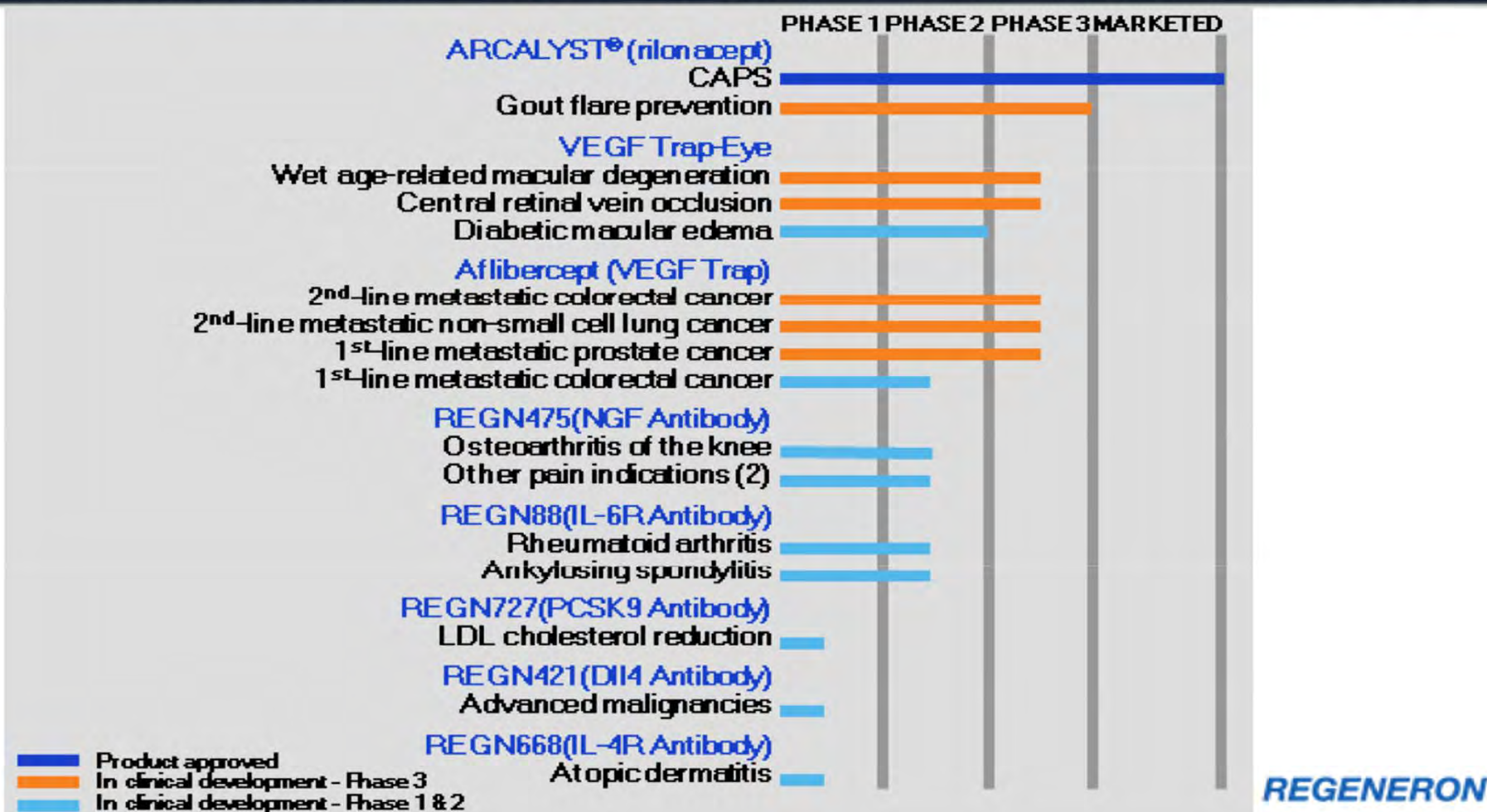
Regeneron Pharmaceuticals Inc. 2010

A mid-sized Biotech

- People: Approx 1500 employees
 - 700 discovery and preclinical development, 230 clinical/regulatory/safety,
 - 400 industrial operations and/or manufacturing
 - 300 Ph.D.s, 25 M.D.s
 - 3 Nobel laureates on board of directors
 - Chief Scientific Officer who is a member of National Academy of Sciences
 - Chairman of Board Roy Vagelos, M.D.



Regeneron Today – Well-Positioned For the Future



REGENERON

Regeneron Today – Well-Positioned Compared to Peers

Rank #	Market Cap (\$M) as of 11/04/2010		R&D Spend (\$M) 2009		Revenue (\$M) 2009		Employees at Dec. 31, 2009	
1	AMGN	\$53,322	AMGN	\$2,858	AMGN	\$14,642	AMGN	17,200
2	GILD	\$32,325	BIIB	\$1,283	GILD	\$7,011	GENZ	12,000
3	CELG	\$29,330	GILD	\$940	GENZ	\$4,516	BIIB	4,750
4	GENZ	\$18,272	GENZ	\$865	BIIB	\$4,377	GILD	3,852
5	BIIB	\$14,894	CELG	\$795	CELG	\$2,690	CELG	2,813
6	VRTX	\$7,065	VRTX	\$550	ELN	\$822	AMLN	1,500
7	ALXN	\$6,585	REGN	\$399	AMLN	\$758	VRTX	1,432
8	DNDN	\$5,202	ELN	\$278	CBST	\$562	ELN	1,321
9	HGSI	\$4,958	EXEL	\$235	ALXN	\$387	REGN	1,029
10	UTHR	\$3,384	AMLN	\$185	REGN	\$379	HGSI	850
11	ELN	\$3,222	HGSI	\$174	UTHR	\$370	BMRN	720
12	BMRN	\$2,654	CBST	\$166	BMRN	\$325	EXEL	676
13	REGN	\$2,375	ISIS	\$135	HGSI	\$276	ALXN	673
14	INCY	\$1,968	ONXX	\$129	ONXX	\$251	CBST	600
15	AMLN	\$1,823	UTHR	\$122	ALKS	\$178	ALKS	570
16	ONXX	\$1,768	SGEN	\$119	EXEL	\$152	DNDN	484
17	THR	\$1,543	INCY	\$119	ISIS	\$122	UTHR	410
18	SGEN	\$1,501	BMRN	\$115	VRTX	\$102	SGEN	289
19	CBST	\$1,399	ALNY	\$109	ALNY	\$101	ONXX	271
20	ALKS	\$1,140	ALKS	\$95	SGEN	\$52	ISIS	250
21	ISIS	\$938	ALXN	\$82	THR	\$24	INCY	221
22	ALNY	\$557	THR	\$78	INCY	\$9	THR	194
23	EXEL	\$484	DNDN	\$62	DNDN	\$0	ALNY	178

Source: Thomson Financial, SEC Filings

REGENERON 27



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Resource Management



1. Resource Planning
2. Portfolio Mgt
3. Tracking Progress
4. Reforecasting



The Resourcing Challenge

- Regeneration at a transition point
 - From smaller, experienced core of individuals, highly centralized and informal systems
 - Company was highly focused on small number of products
- Multiple products, multiple work streams
 - To greater de-centralization and more structured processes
 - Critical resourcing challenges



Regenron's approach to developing a Resource Management System

- Build a small internal group with expertise
- Identify a project champion
- Identify your key systems of record
- Educate the key stake-holders
- Do this while running the business



Need for key fundamental pieces of information

- Know your book of business
- Know your biggest areas of variability
 - BLAs
 - Clinical Studies
 - Pre-clinical candidates
- Develop standard algorithms for predicting resource owned by the functions
- Develop a forward looking process that is looking at least 12 to 18 months ahead



Critical Business Standards

- Standardized Gantt charts and milestones
- A robust way to capture resource utilization
- A forum to agree priorities and to discuss resourcing conflicts.
- Develop an understanding of what is Core and Non-core to your business
- Develop a strategy for using flexible resources



Resource Management



1. Resource Planning
2. Portfolio Mgt
3. Tracking Progress
4. Reforecasting



Portfolio Management

- An issue that needs to be dealt with
 - Currently principally governed by needs of collaborators portfolios



Tracking progress

- An appropriate CTMS System
 - Siebel
 - Impact
 - Etc
- An enterprise project Management System
 - Planis Ware
 - Microsoft project based



When, How, and Why: Optimizing resource planning to get the most from your existing resource

John Sneed
Senior Director, Project
Management
Quintiles



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Who: Quintiles

- CRO – Major Service Provider
- 23,000 Staff, 100 Offices, 60 Countries
- 1000's of Projects
- Constant Change



Why: Quintiles Resource Planning

- By providing globally standardized project and resource data, project teams can focus on value-added activities and effective, data driven business solutions
- RM + PPM = QRPM
 - Resource **M**anagement
 - Project and **P**ortfolio **M**anagement



What: Resource Management

- Staff: Billable/Non-Billable
- Tools: Enterprise Resource Management
- Management Focus:
 - Profitability
 - Utilization
 - Net Revenue



What: Project and Portfolio Management

- Staff: Program/Project team
- Tools: CTMS, Excel, MS Project, Meetings!
- Management Focus:
 - Allocation
 - Realization
 - Budget/Actual
- Portfolio/Program Tracking Critical



How: Real World Example

	Jan 2011 Status	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11	Jan-12
		20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
16003 Phase I	Enrolling Expansion Cohort	1	1	1	2											
16004 Phase I	Enrolling - MTD Identification	14	15	1	2	3	4	1	2							
16005 Phase I		4	5	1	2	3	4	5	6	7	8	9	10	11	12	1
16005 Phase II		4	5	6	7	8	1	2	3	4	5	6	7	8	9	10
16006 Phase I		1	2	3	4	5	6	7	1	2	3	4	5	6	7	8
16006 Phase II												1	2	3	1	2
16008 Phase I																
16008 Phase II																
1600X Phase I	Planning															
1600X Phase II	Planning															

Proactive Resource Allocation

- Program FTE Tracker
- Identify over/under allocation time points
- Allocate resources based on Sponsor, indication, relevant experience



When, How and Why: Optimizing Resource Planning to Get the Most from Your Existing Resources

Deborah Bisio Dwyer

Associate Director,
Outsourcing
Cerexa, Inc.



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Cerexa



- Spin-out from Peninsula Pharmaceuticals in Jul'05
- Acquired by Forest Laboratories in Jan'07
- Approx 80 employees, located in Oakland, California
- Anti-infective focus
- Multiple projects in development
- Product approval (October, 2010)
 - **Ceftaroline (Teflaro™)**



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Resource Management

- Portfolio Management
 - Long Range Planning
- Resourcing Planning
- Tracking Progress
- Reforecasting



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Cerexa: Establish Fiscal Year 2012 Goals & Long Range Planning

- Look at our upcoming project areas and goals
- Focus on the activities of product development variability
 - Pre-clinical candidates
 - Pre-clinical studies
 - Clinical Studies
 - Longer ranging plans
- Utilize internal tools for predicting outsourcing or insourcing needs (per functional area)
- Review a multi-year development plan



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Fiscal Year (FY) Budget Kick Off

- *Establish Cerexa FY Goals*
- *Key budget and Reforecast cycles*
- *Review Budget templates*
- *Review Clinical Development plan*



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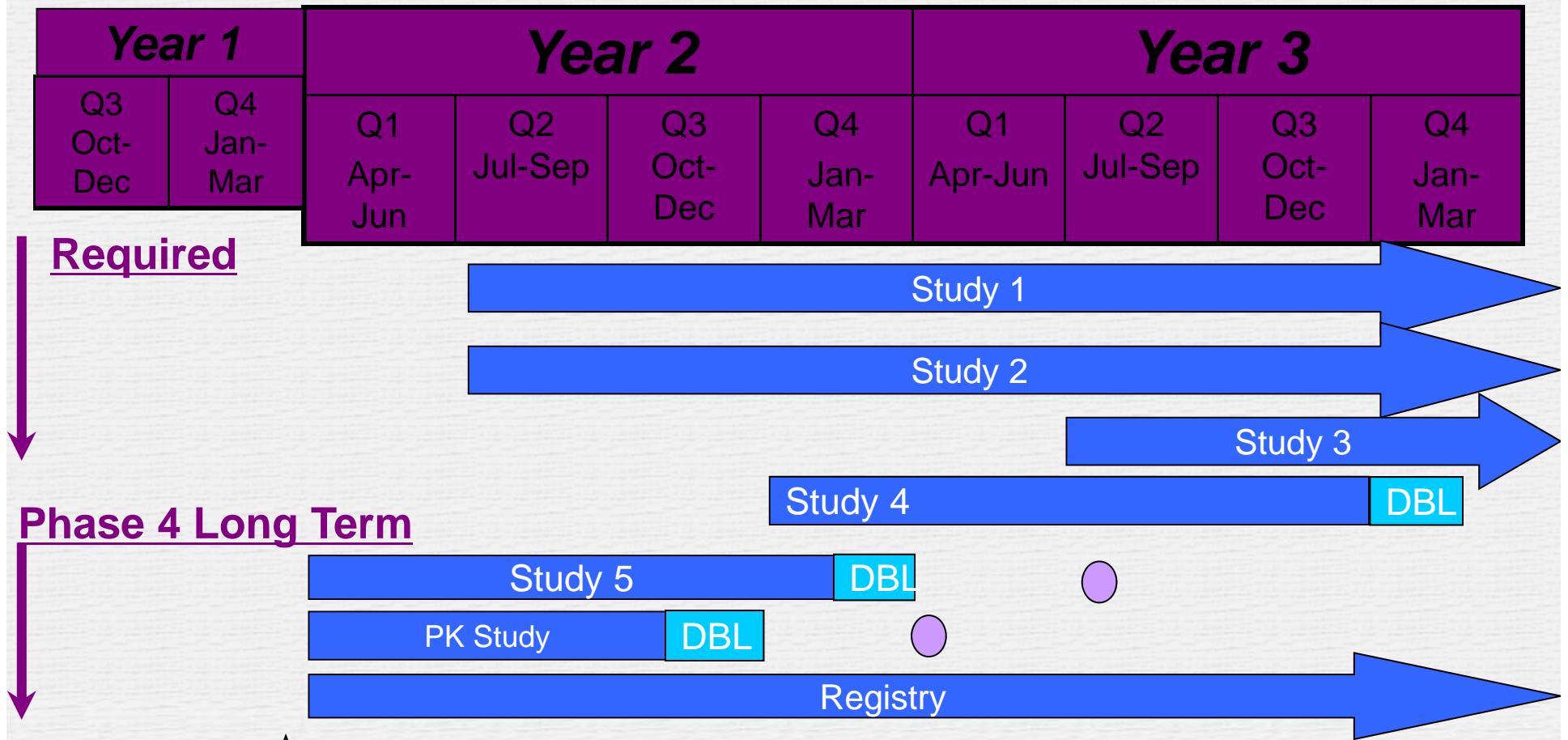
Project Activities and Timelines

Functional Group	Study	Comments	# Subjects (may be estimate)	Study activity start	FPI	LPO	DBL	CSR
Clinical Studies								
Micro								
Tox								
CMC								



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Multiyear Timeline (Clinical)

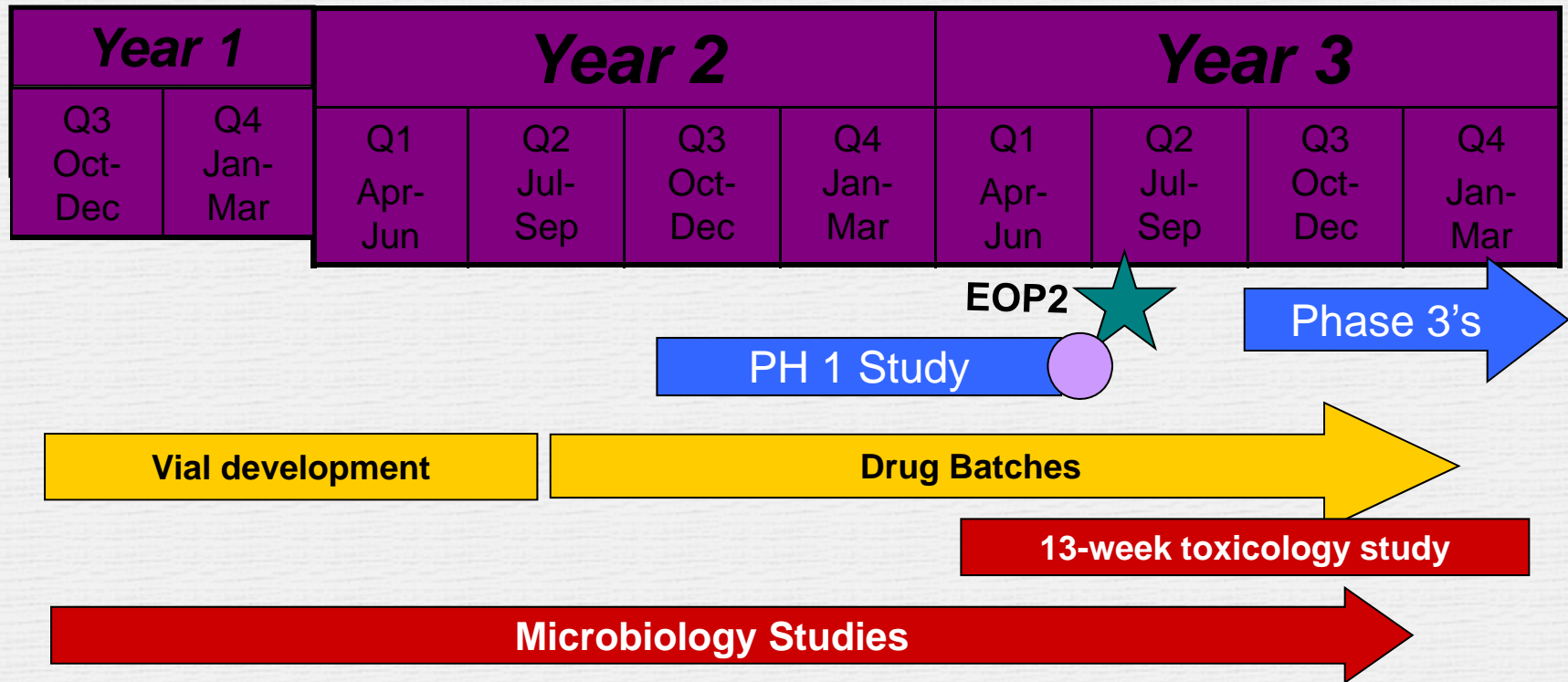







- Clinical
- CMC
- Non-clinical
- ★ Reg Filing
- CSR

•Key Uncertainties

- Final Commitment w/ FDA
- Superiority study combined with CAP-MRSA study?

Multiyear Timeline (Clinical)



-  Clinical
-  CMC
-  Non-clinical
-  Reg Filing
-  CSR

- ### Key Uncertainties
- Full Enrollment per timeline
 - Low risk uncertainty on single-vial stability

Review Key Dates for Budget and Reforecast

Fiscal Year 2012 Budget Timelines

- Week 1 Budget templates sent out
 - Week 2 Draft budgets due to finance
 - Week 3 Internal resource estimate due to finance
 - Week 4 Leadership team meeting- review budget
-
- Reforecasting is done 4 times per year (May Reforecast, 3+9, 6+6, 9+3)



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Headcount Additions

Cost Center:

Owner:

	<u>Position/Title</u>	<u>Base Salary</u>	<u>Start Date</u>	<u>Primary Job Duties/ Program supported</u>
1)				
2)				
3)				
4)				
5)				
6)				
7)				



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Opportunities and Risks

Cost Center:
Owner:

<u>Program/trial impacted</u>	<u>Potential event</u>	<u>Estimated Expense impact Increase/(Decrease)</u>
1)		
2)		
3)		
4)		
5)		
6)		
7)		

Purpose: This page highlights significant events which reasonably may occur and which would have a significant impact upon the planned rate of spending

Contractors (Temps, Outside Consultants, General Consultants)

Cost Center name:

Cost Center number:

						Summary				
						Q1	Q2	Q3	Q4	Total
Total Requested Budget:						\$ -	\$ -	\$ -	\$ -	\$ -

Payment Type	Location	Program	Study	Role	Resource Type	Vendor	Resource Name	Cost Per Unit	Units of	
									Q1	Q2

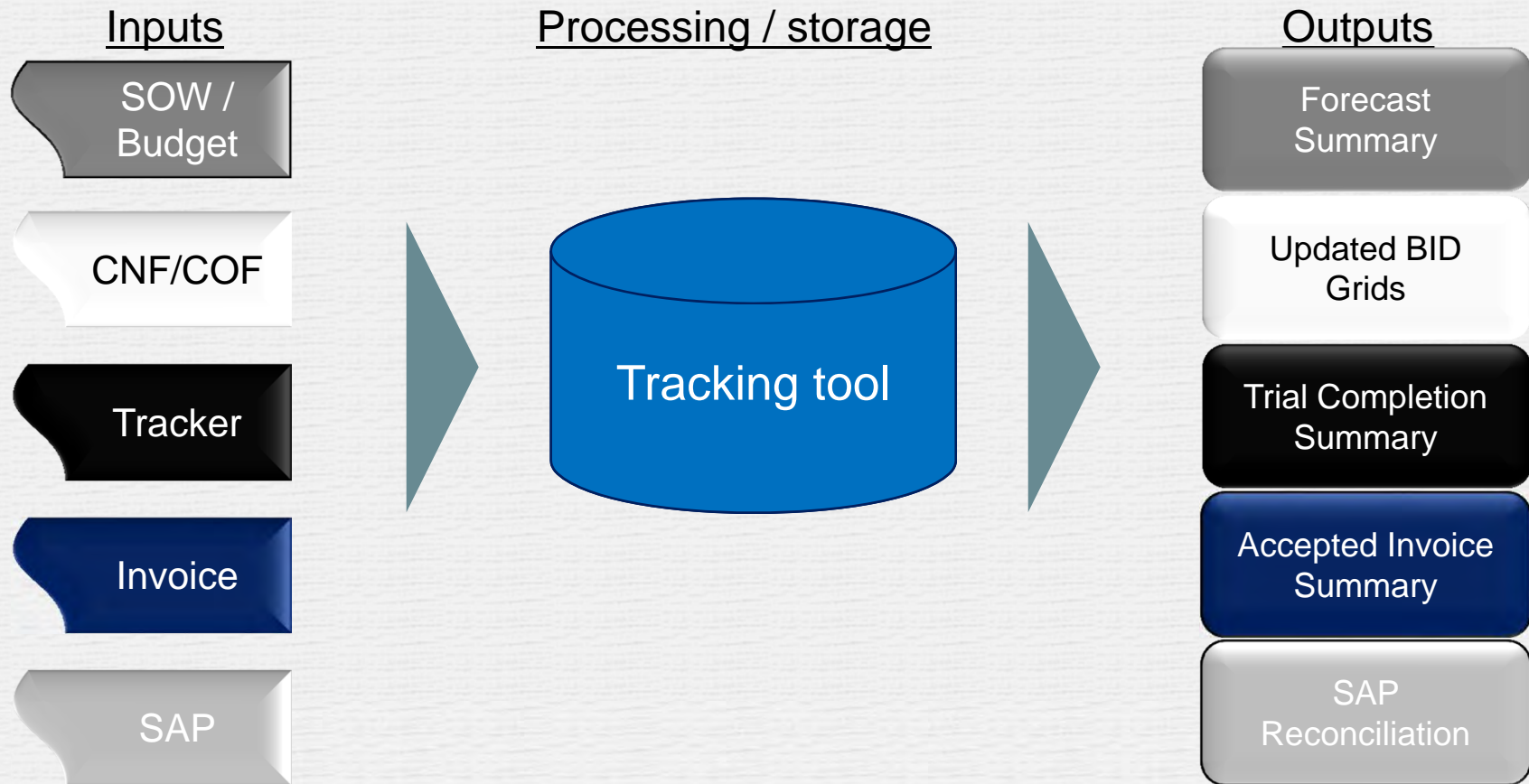
Tracking Study Progress



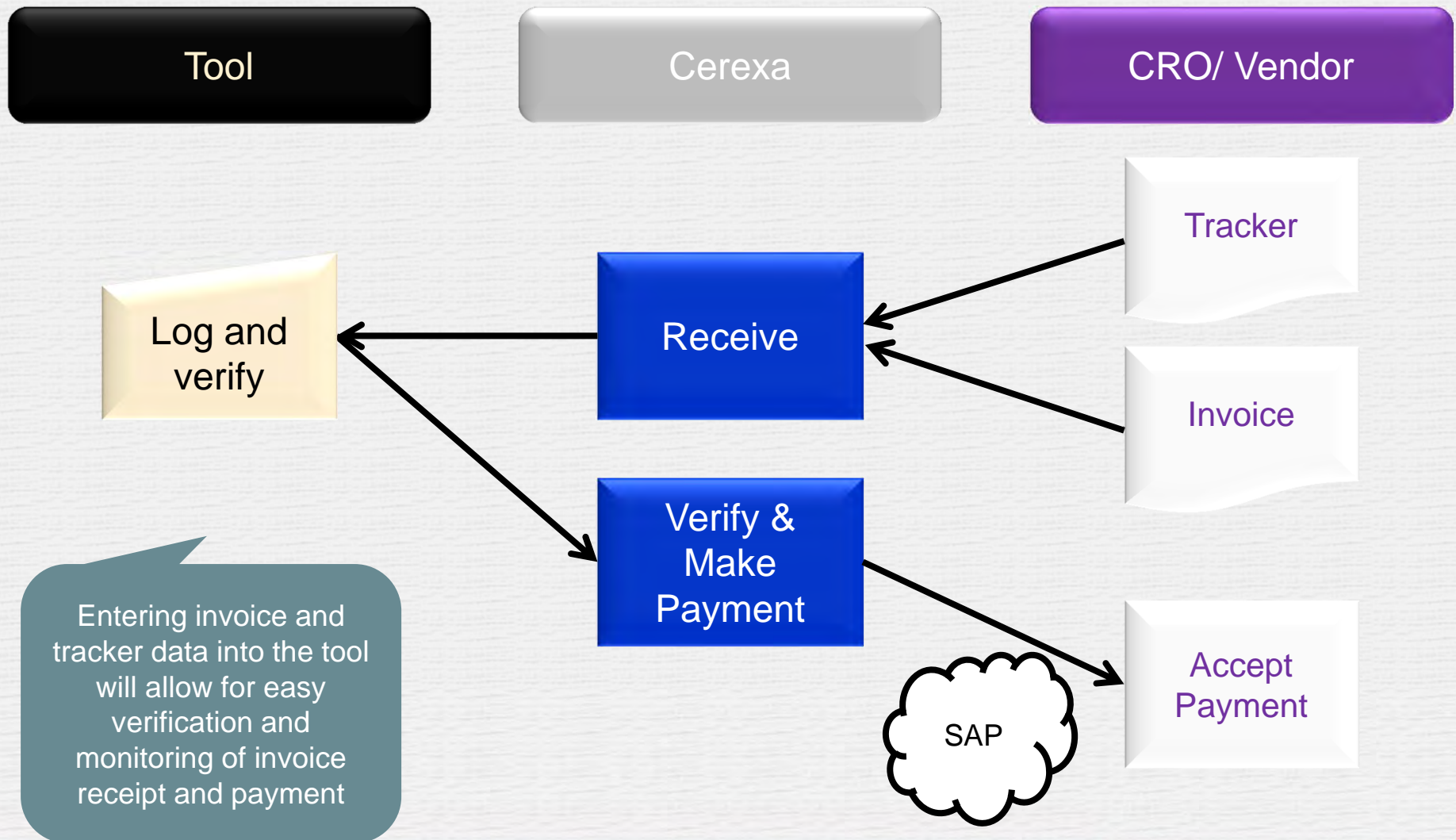
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A Tool that provides vendor tracking data and automates analysis and reporting



As the trial progresses activities are verified so that invoices are paid



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Total Cost Tracking Tool

Clinical Trial Cost Tracking Tool

Trial Management

Select

Update Trial Progress:

- Log CNF/COF
- Update Tracker
- Record Milestone Achievement
- Add Invoice
- Lock LE
- Close Trial

View Trial Specific Outputs:

- Calculate Forecast
- View Current Completion
- View Current BID Grid
- View Forecast History
- View Prepayment Allocation
- View Accepted Invoice History
- View LE History
- View All Comments

View Not Trial Specific Outputs:

- View Dashboard
- View Verification History
- View Unexecuted CNFs/COFs
- View Unassociated CNFs
- View CNF/COF Summary
- Vendor Summary
- Detailed Report
- Executive Summary

Maintenance (not Trial-specific)

- Configuration
- Import Actual Payments from SAP



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Conclusion - Four Pillars

- Portfolio Management
 - Long Range Planning
- Resource Planning to the Projects
 - Utilize the budgeting tools to identify the needs of the projects
 - Outsource a great deal
- Tracking Study Progress
- Reforecasting
 - Ability to change our forecasts



Thank You!



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