A Systems Approach to Resource Allocation in an Integrated Research and Development Environment

CA Walawander, TH Grasela, B Ruhland, P Vecchione

Cognigen Corporation, Buffalo, NY
cognigencorp.com

ABSTRACT

Typically, at the beginning of a project, the scope is defined along with the timelines and budget. As project team leaders negotiate with functional managers to recruit key team members, including outsourced resources, the ad hoc approach to team recruitment often results in critical gaps in required skills or resources. This can result in missing or inadequate information at major decision-making milestones. Model-based drug development (MBDD) provides an basis for continually performing gap analyses during the lifecycle of development, including team recruitment. Models defining the determinants of drug outcomes can be used to integrate the specialized and varied scientific resources around a central concept based on understanding the determinants of drug efficacy and safety. In adopting MBDD, the integrated project team (IPT) must ensure that all team members contribute to the gap analyses and the design of experiments required to address these gaps. Thus ensuring team-wide knowledge sharing and facilitating the incorporation of scientific and medical expertise.

The IPT decision-making functions around a core set of modeling and simulation processes that continually generates and refines the signals emerging from early development studies and identifies the knowledge gaps that must be addressed in future studies. At a minimum, the core processes supporting the IPT can be used to define the inputs and outputs that must be supplied by the various R&D functions that best meet the needs of upstream and downstream stakeholders .

As the R&D functions acquire data that add value to the models enabling them to be more predictive of future outcomes, the models can be used to project the future value of a product and provide a basis for defining project priorities within a portfolio and determining how resources are to be allocated across the IPT. The models also provide a feedback loop to the team in terms of objective criteria for decision-making at critical stage gates and assistance in designing optimal future trials. These feedback loops and the subsequent specification of required knowledge to close gaps serve as an important organizing basis for team planning and resource allocation.

A strong integrated function, such as MBDD, within an organization can change the way resourcing of projects is thought about and allocated.

TRADITIONAL RESOURCE ALLOCATION

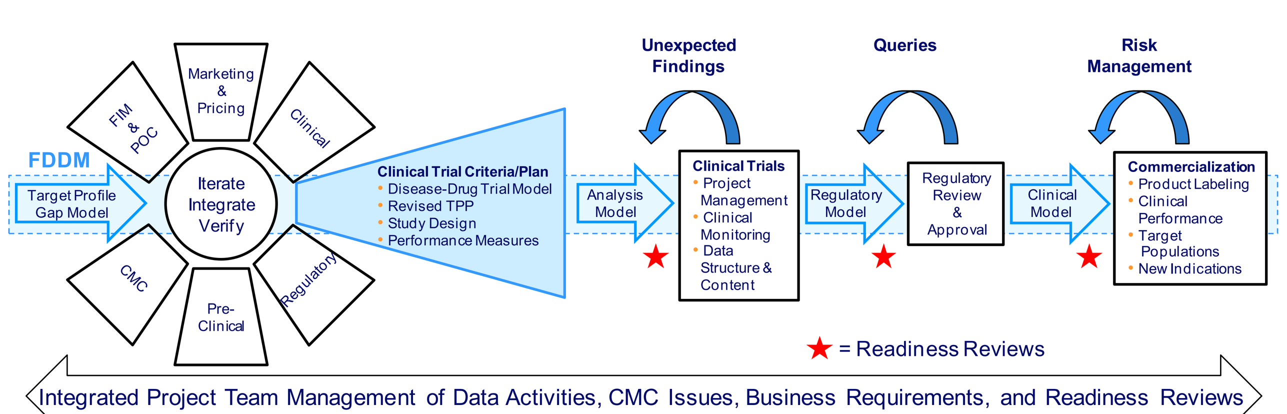
- Single and uni-dimensional hierarchy of function and products often deployed via a matrix organization.
- Simple governance structure for decision-making.
- Resources are allocated largely through a centrally designed non-structural context.
- Project management has relatively well-defined scope definition and timelines, but limited understanding of required skills and resources.

SYSTEMS APPROACH TO RESOURCE ALLOCATION

- A systems approach to resource allocation will
  - Identify with one's external orientation, as well as internal;
  - Understand the leverage points that will influence change, where needed;
  - Permit a fluid decision-making process that can adjust to external factors or new knowledge and provide a disciplined and fair internal decision process that creates mutual understanding and transcends stagnation; and
  - Create aligned processes through a systematic evaluation of process and knowledge flow.

INTEGRATED RESEARCH AND DEVELOPMENT ENVIRONMENT

Integrated Project Team



A Transformation and Its Pay-Off

Early Development
- Multi-functional, iterative development
- Co-located integrated project team
- Cost vs. benefit driven strategy
- Franchise disease-drug trial model (FDDM) continually updated
- Robust informatic infrastructure

Product Development & Commercialization
- Improved productivity
- Higher quality data = less uncertainty
- Shorter schedule, lower cost
- Higher regulatory approval rate
- Smarter risk management

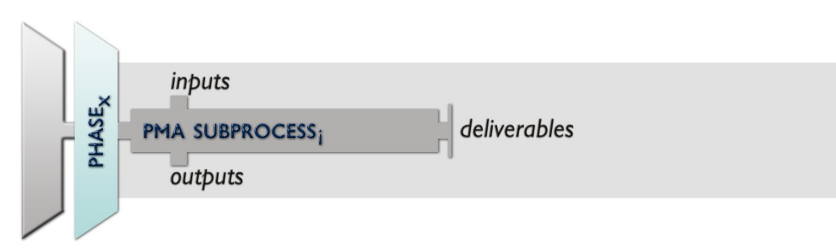
- Functional departments within the biopharmaceutical industry are highly differentiated by the scientific specialties that are brought to bear on the drug development process.
- Traditionally, incentives and performance are often based on quantity of production and moving the product to the next stage gate of development.
- The integrated project team concept presented in the above figure illustrates parallel development programs where feedback loops (both positive and negative) are incorporated into the process to share knowledge across studies and development programs to improve decisions and reduce wasted effort.

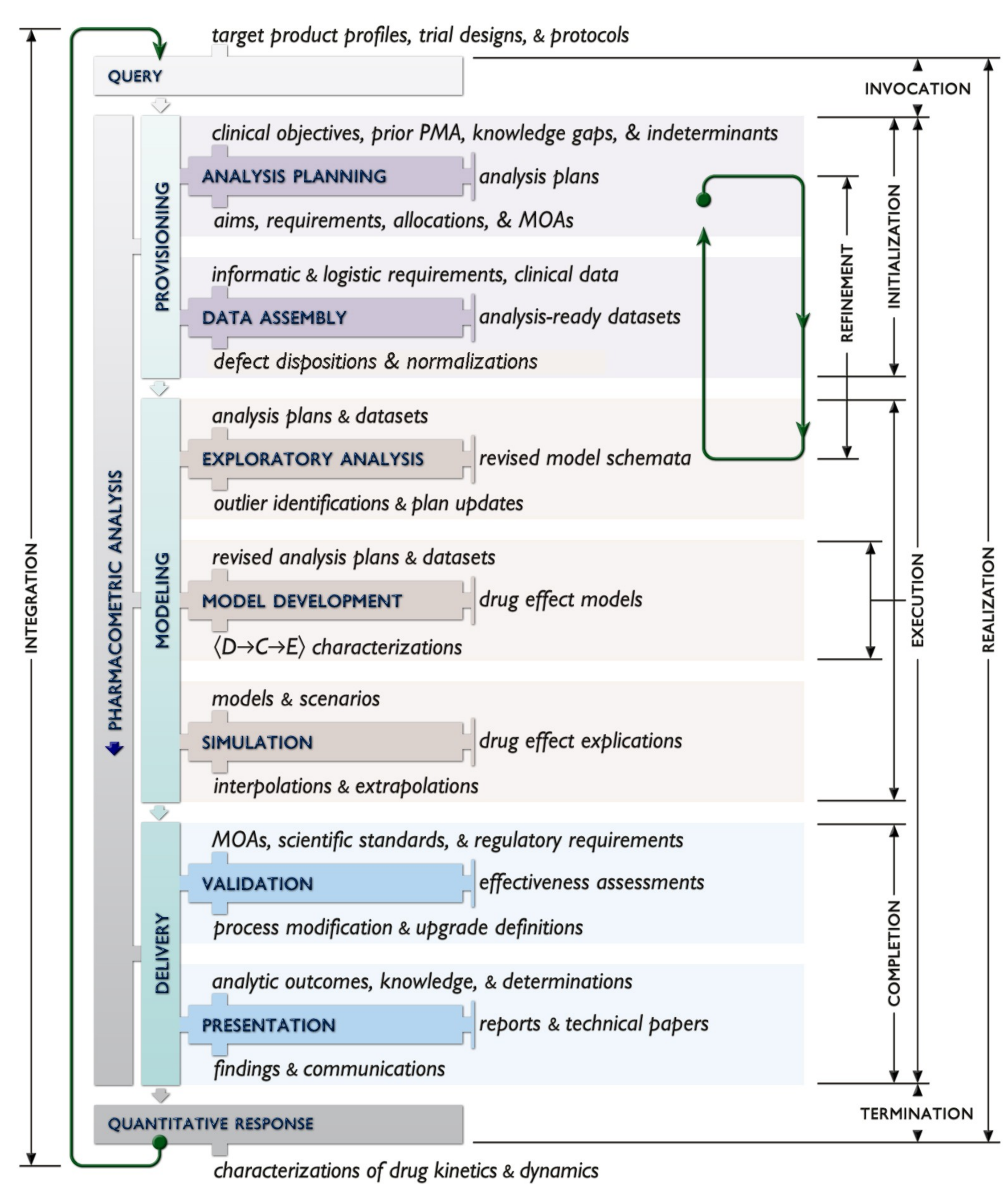
RESOURCE ALLOCATION DRIVES OUTCOME

- Outcomes are determined by where resources are allocated and how processes are executed.
- Mid-level managers can influence strategic outcomes.
- Structure of an organization shapes resource allocation so, therefore, structure shapes strategy.
- Over time, small decisions trigger a sequence of increasingly important decisions.

MODEL-BASED DRUG DEVELOPMENT AS THE INTEGRATING PROCESS

Modeling and Simulation Process

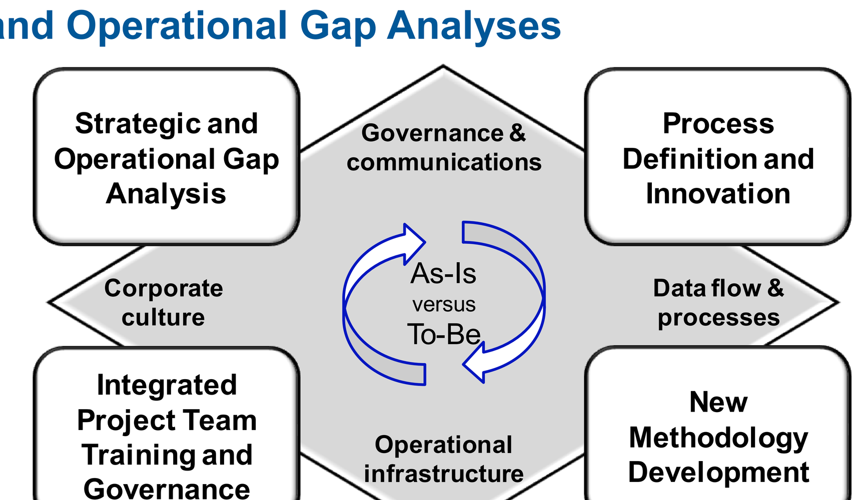




MOA – Measures of acceptability
D→C→E – Drug→Concentration→Effect
PMA – Pharmacometric analysis

- A paradigm, such as modeling and simulation, is an integration strategy that brings together the highly differentiated specialties in the biopharmaceutical environment around a core development strategy based on developing a clear understanding of the determinants of drug safety and efficacy.
  - It is a fully-integrated, collaborative, and multidisciplinary approach to research and development using integrated project teams for program design, analysis, and interpretation.
- An integrated project team can only be successful when inputs to the process are specified and assimilated and outputs are fed back to the integrated project teams in a way that will enhance their decision-making process.
  - This requires an ever expanding knowledge base that can further enhance the decision-making at various milestones.
- A disease modeling and simulation platform provides the Program Lead with a basis for performing a gap analysis that can be used to mobilize and allocate resources.
  - Subsequent generation of missing pieces of information, and recognition of further gaps enables mobilization of team members and solicitation of additional resources to close these gaps.

Strategic and Operational Gap Analyses



- The integrated project team functions around a core set of processes that continually works to identify and refine the patterns and signals emerging from the models developed in early development studies and carries forward the knowledge gaps that must be addressed in future studies.
- Existing processes need to be realigned to an integrating function and a defined, consistent knowledge architecture needs to be developed that aligns knowledge flow within projects and for their integrated project teams.

RESOURCE ALLOCATION MODEL

Resource Allocation Model For Modeling and Simulation Projects

				Diease Franchise 1	Disease Franchise 2	Disease Franchise 3	Disease Franchise 4	Disease Franchise 5
Anticipated Hours to Perform Project				6000	2000	900	1200	1700
% of time in current year				50%	60%	50%	56%	56%
% of time in future years				50%	40%	50%	44%	44%
Data Programming:		25%						
Data Assembly and Exploratory	**scientific**		15%	225.00	75.00	33.75	45.00	63.75
Analysis	**non-scientific**		85%	1275.00	425.00	191.25	255.00	361.25
Analysis		40%						
Model Development, Simulation,	**scientific**		80%	1920.00	640.00	288.00	384.00	544.00
Validation	**non-scientific**		20%	480.00	160.00	72.00	96.00	136.00
Reporting		25%						
Analysis planning, presentation,	**scientific**		65%	975.00	325.00	146.25	195.00	276.25
	non-scientific		35%	525.00	175.00	78.75	105.00	148.75
Project Management		10%						
	scientific		40%	240.00	80.00	36.00	48.00	68.00
	non-scientific		60%	360.00	120.00	54.00	72.00	102.00
scientific total				3360.00	1120.00	504.00	672.00	952.00
nonscientific total				2640.00	880.00	396.00	528.00	748.00
scientific total in current year				1680	672	252	376.32	533.12
scientific total in future year				1680	448	252	295.68	418.88
nonscientific total in current year				1320	528	198	295.68	418.88
nonscientific total in future year				1320	352	198	232.32	329.12

	% of time spent on M&S projects	*# of FTEs*
Scientific FTEs for current year	60%	**2.82**
Scientific FTEs for future years	60%	**2.48**
Nonscientific FTEs for current year	50%	**2.65**
Nonscientific FTEs for future years	50%	**2.34**

- The resource allocation model of human capital still needs to be utilized for individual projects, but the models should be developed to align with the integrating function and tie together the differentiated specialties and assure the knowledge asset is being distributed across the lifecycle.
- After a system is realigned in its allocation of strategic resources according to an integrating strategy, projects will be better defined as the integrated project teams will know where their piece is fitting into the integration and what they can expect to get out of the disease franchise models and simulations, thereby reducing re-work and having more efficient, targeted projects.

NEXT STEPS

- More dynamic resource allocation models need to be developed to reflect the complexity of multinationals or interconnected large and small businesses with their subsidiaries or strategic alliances.
- With the economy as it is today, more effort needs to be put into integrating strategies that will mobilize knowledge across and between organizations in a fluid and dynamic manner.
- New management and incentive structures need to be put into place that reward knowledge sharing and optimizing resources across the organization.

SUMMARY

- Resource allocation needs to be evaluated first from a systems perspective.
  - The structure of an organization and where resources are allocated in that structure will shape strategy.
  - In our increasingly complex and global organizations, the fluid mobilization of the knowledge asset will determine the successful organizations.
- Therefore, as the research and development functions acquire data and information that add value to the disease progression models, it is the supply and demand market force of the most innovative and most impactful development programs that will define the priorities and strategies and where resources are allocated for the integrated project team.

REFERENCES

1. Bolman LG, Deal TE. *Reframing Organizations: Artistry, Choice, and Leadership.* 4th ed. San Francisco, CA: Jossey-Bass; 2008.
2. Bower JL, Gilber CG. *From Resource Allocation to Strategy*. New York, NY: Oxford University Press; 2007.
3. Grasela TH, Dement CW, Kolterman OG, et al. Pharmacometrics and the transition to model-based development. *Clin Pharmacol Ther*. 2007;82:137-142.
4. Grasela TH. Concepts, technics, and services for implementing model based drug development. Unpublished data.

Walawander CA, Grasela TH, Ruhland B, Vecchione P. A systems approach to resource allocation in an integrated research and development environment. Poster presented at: PMI Pharmaceutical Specific Interest Group (PharmaSIG) Annual Meeting; March 15-17, 2010; Philadelphia, PA.

♦♦♦♦♦♦♦♦♦♦♦

For additional information, please contact
Cynthia A. Walawander, MA, PMP
Executive Vice President and COO
Cognigen Corporation
395 South Youngs Road, Buffalo, NY 14221
(716) 633-3463, ext. 229 or cindy.walawander@cognigencorp.com