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Case Study:
An R&D Asset Development Decision
Utilizing Lilly's Quality Decision Process

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Answers That Matter.

Quality Decision Process

Background

Part of R&D Transformation Agenda

From:

- “Advocacy” model of business case presentation for Key Decisions in R&D.
- Majority of time devoted to team presentation. Limited time for decision board discussion.
- Project level considerations only.



To:

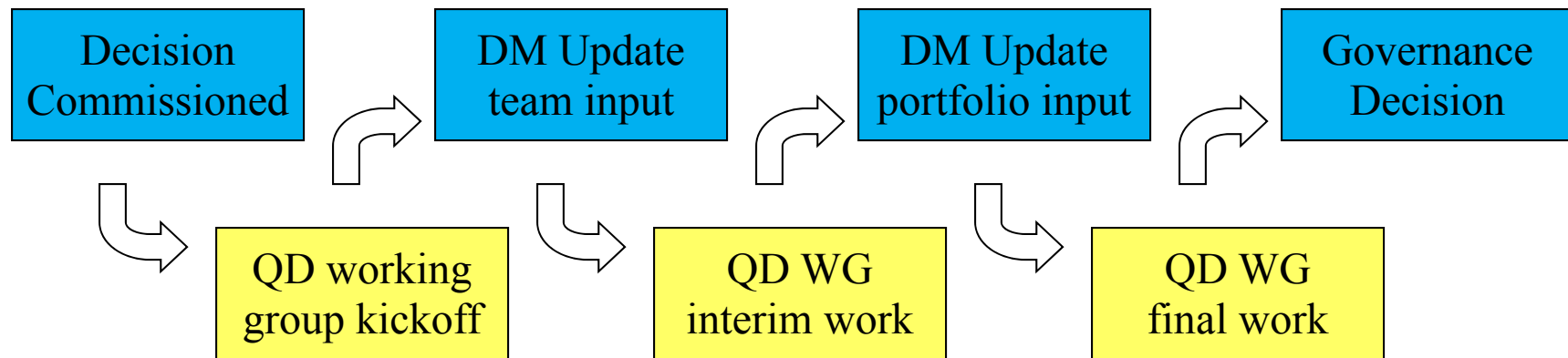
- Presentation and discussion of alternatives and evaluation of values, uncertainties and tradeoffs.
- Decision board informed of evaluation of alternatives and team recommendation, then dedicated time for decision board deliberation.
- Portfolio level considerations.

How:

- Quality Decision Making course: Training for project managers and decision boards to enable shift to unbiased consideration and evaluation of alternatives.
- Key Decisions: List of upcoming “Key Decisions” is managed by R&D Project Management and Finance with strong engagement by governance committees.
- ★ Quality Decision Process: Process facilitated by Decision Sciences consultants for “Key Decisions” to enable key elements of decision quality, including generation and evaluation of alternatives, alignment with stakeholder values, etc.

Quality Decision Process

The process



Communication between the Decision Board and the QD working group needs to be clear up front at the time that the decision is commissioned, and allow for regular feedback to the Decision Board to assure that the working group is on track with the decision makers' expectations.

An inventory of key upcoming decisions will be kept so that each decision can be kept in context for the decision makers.

Guideline of approximately 2 months for the process

The Key Decision

“Asset A”

Background:

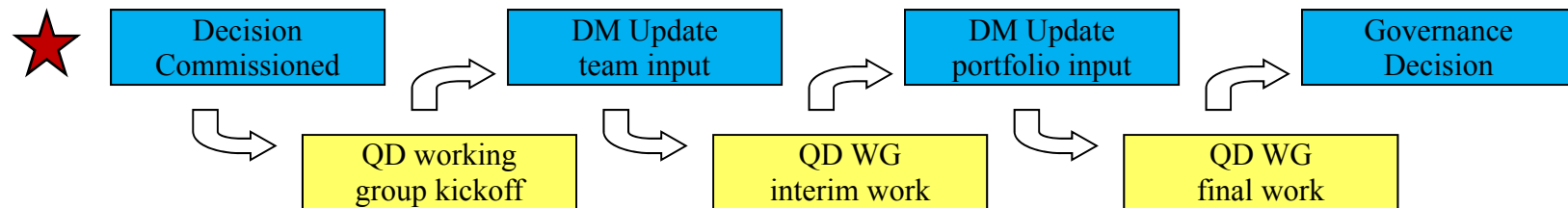
- Internal asset with multiple indications
- Lead indication: recent phase 2 data
 - Earliest launch
 - Lower “value” indication
- Other indications: earlier in development (phase 1)
 - Later launches
 - Higher “value” indications
 - Challenges of viability of other indications, currently low p(TS)
 - Key uncertainties to be resolved in 2010

Decision (initial frame):

- Should we invest in phase 3 development for the lead indication
- Decision board scheduled for 2 ½ months away

“Asset A”

Quality Decision Process

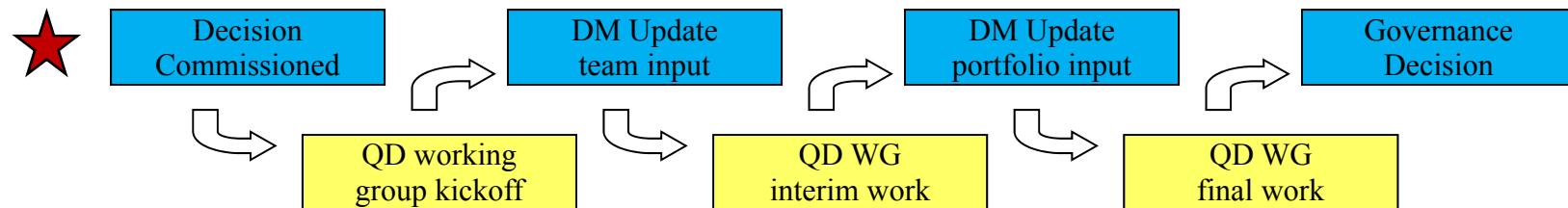


Prior to Decision Commissioning:

- Meet with Project Manager for the team:
 - Background on the asset
 - Describe the Quality Decision Process
 - Discuss elements of alternatives the team is considering
 - Schedule Decision Commissioning
- Takeaways:
 - Team understands process and intent
 - However, team has clear momentum strategy and is unsure of what alternatives might need to be explored
 - Meeting with FDA upcoming to review team proposed development plan
 - Decision Commissioning scheduled

“Asset A”

Quality Decision Process

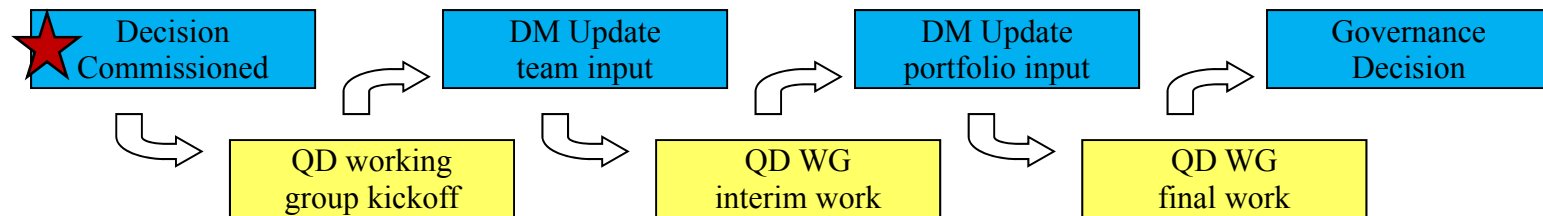


Decision Commissioning 2 days away:

- FDA feedback:
 - Team’s momentum strategy is not recommended by FDA
 - FDA suggests a modification to team’s momentum strategy
 - higher cost, longer trial than momentum strategy
 - FDA also suggests another alternative development plan to consider
- Takeaways:
 - Team needs to regroup and digest FDA feedback
 - Decision Commissioning rescheduled for 3 weeks later
 - Team now considering two development alternatives
 - “Elements” of alternatives prepared for Decision Commissioning



“Asset A” Quality Decision Process



Decision Commissioning:

- Who:
 - Key governance committee chair (sponsor)
 - Senior leaders of project management and finance
 - Decision Sciences representation
 - Team’s project manager
- What:
 - Review recent “Asset A” background, including FDA conversation
 - Discuss “elements” of alternatives (development plan, wait, other indications)
 - Discuss values to consider (NPV, launch timing, p(S), costs, development risks)
- Takeaways:
 - Two clear decisions to consider; values to use in evaluation understood

“Asset A”

Decision Commissioning Takeaways

Scope:

- Primary scope: Phase 3 development of lead indication
- Consider: how other indications are linked to this decision (technical frame, business frame)

Alternatives:

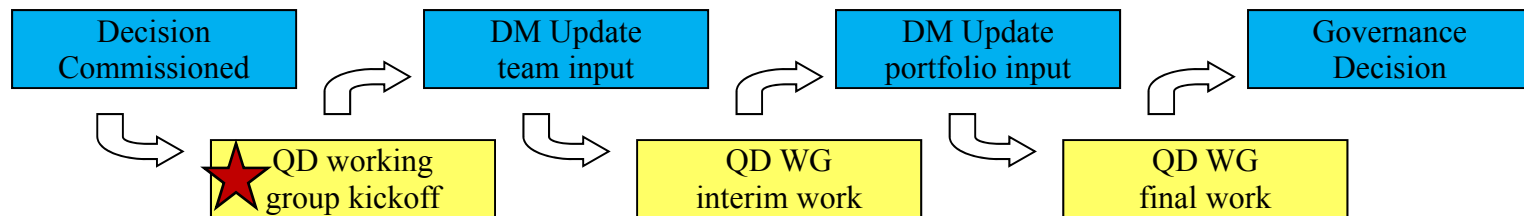
- Development plan 1 (modified, longer, more expensive version of momentum plan)
- Development plan 2 (exploring different patient population than phase 2 study)
- Delay to resolve uncertainty on other indications

Values:

- Traditional portfolio metrics: time, cost, value/eNPV, technical risk/p(TS)
- Budget impact (pre-YZ, YZ, post-YZ)
- Strategic fit – how does this decision fit within therapeutic area, are there any dependencies or links to other assets.

“Asset A”

Quality Decision Process



Quality Decision Working Group Kickoff:

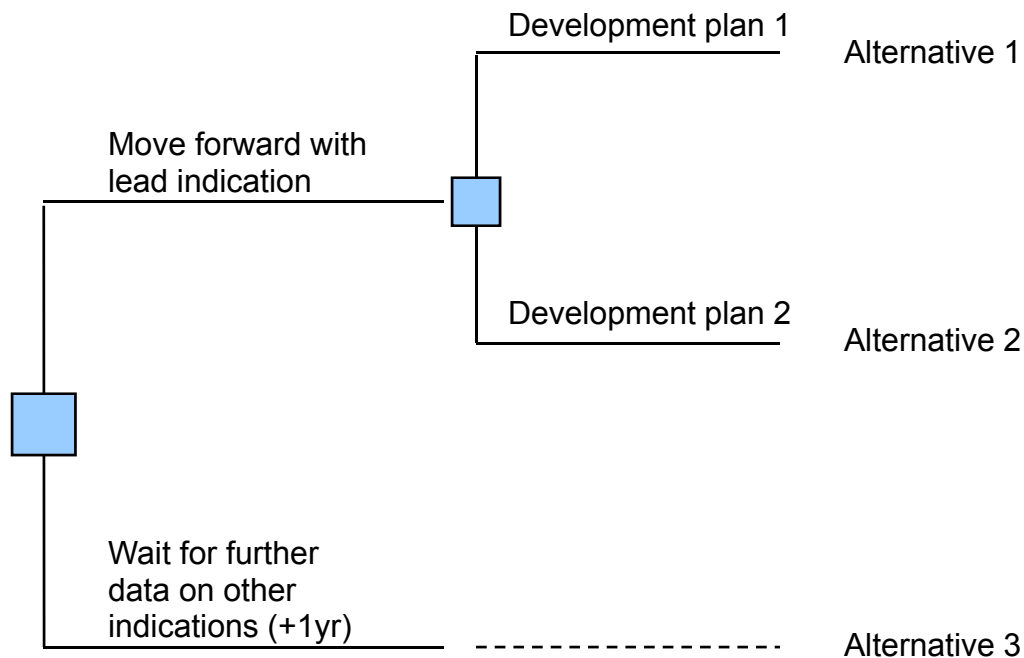
- Who:
 - Decision Sciences representation
 - Team’s project manager and associate
 - Finance, Marketing/market research, capacity management
- What:
 - Review Decision Commissioning takeaways
 - Develop timetable (very tight now with 3 week delay in commissioning)
- Next steps:
 - Team: “flesh out” alternatives
 - Others: prepare to evaluate alternatives

“Asset A” Decision Frame

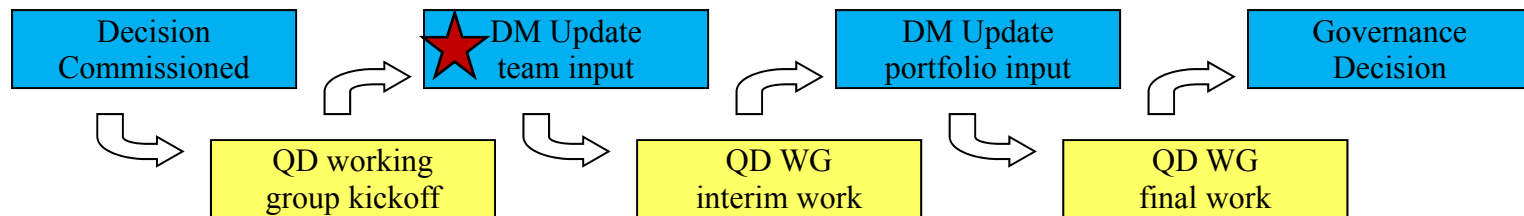
Current Decisions

Decision: Do we move forward with lead indication now or wait for more certainty on other indications?

Decision: If we move forward with lead indication, should we pursue development plan 1 or 2?



“Asset A” Quality Decision Process

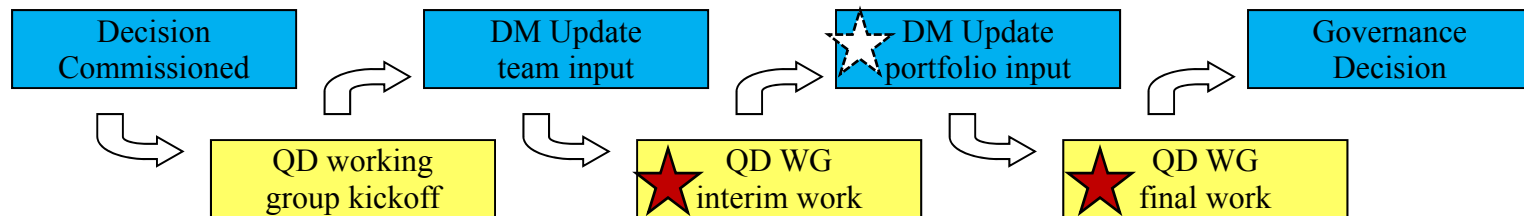


Decision Maker update:

- Who:
 - Same as decision commissioning
- What:
 - Does Decision Maker agree with final frame and alternatives to evaluate?
- Takeaways:
 - Agreement on proposed frame and alternatives
- Next steps:
 - Evaluation of team alternatives
 - Understand portfolio implications

“Asset A”

Quality Decision Process



Quality Decision Working Group:

- What:
 - Evaluation of alternatives: NPV, $p(S)$, timing, costs, risks leveraging existing processes and approval bodies as appropriate.
 - Local governance reviews, especially feasibility of development plans and resource needs.
- Takeaways:
 - Evaluation of the team alternatives complete with clear trade-offs
 - Local governance did not indicate any portfolio implications from the budget or resource needs of the alternatives. Thus, no portfolio alternatives considered.
 - Team considering what alternative to recommend
 - Project Management leader on Governance Board given background and agenda to facilitate the Governance Decision meeting

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Evaluation of alternatives

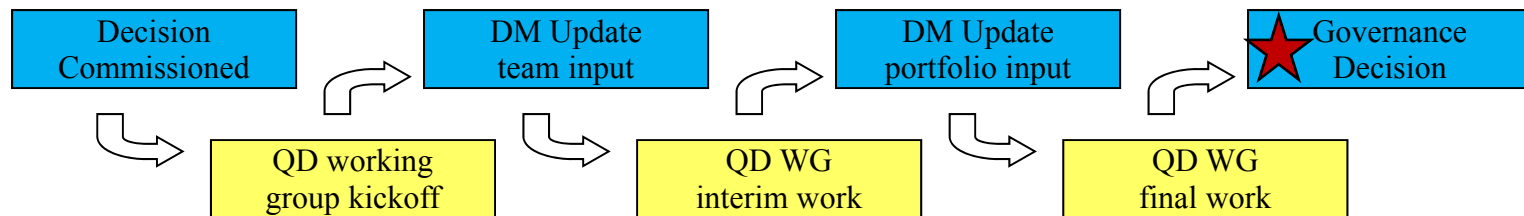
Alternatives	FRD	Launch	2 yr Costs	Total Costs	p(TS)	eNPV	NPVITS	5 th Year Peak Sales
Alternative 1	x	y	\$\$	\$\$\$	z%	\$	\$\$	\$
Alternative 2	x	+3months	\$	\$\$	z%	\$\$	\$\$\$	\$\$
Alternative 3	+18months	+18months	\$	\$\$\$	z%	~0	\$	\$
Indication B	+2yrs	+2yrs			5-10%	~0	\$\$\$\$\$	\$\$\$\$\$
Indication C	+1.5yrs	+1.5yrs			5-10%	~0	\$\$\$	\$\$\$
Indication D	+1.5yrs	+1.5yrs			5-10%	~0	\$\$\$	\$\$\$

Takeaways: Alternative 1 is more expensive and less value, but shorter. Despite official probability being the same as alternative 2, team believes alternative 1 is less “risky”. Other indications have very low p(TS).

Team recommendation: Pursue Alternative 1.

“Asset A”

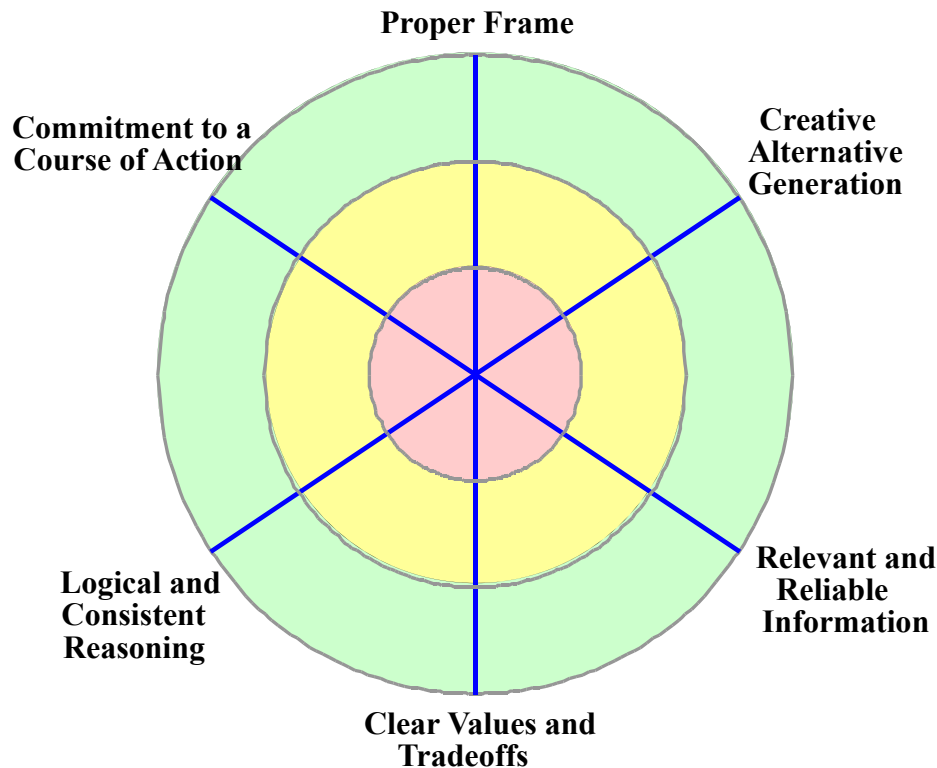
Quality Decision Process



Governance Decision:

- Who:
 - Most senior governance body, responsible for major portfolio decisions
 - Head of R&D and heads of all major functions and therapeutic areas within R&D
- What:
 - Team reviews science and base business case
 - Team reviews alternatives, evaluation of alternatives and team recommendation
 - Discussion by Governance
- Takeaways:
 - After significant discussion (especially around perceived differences in probability of success between alternatives 1 and 2 and risks of the other indications not making it to launch), the Decision Maker ultimately decided to support the team recommendation and approve Alternative 1.

“Asset A” Decision Quality survey



Comments

What were your biggest concerns with the decision process (red area)?

What could be done to make the next decision better (yellow area)?

What did you like most about this decision process (green area)?

Proper Frame

- Purpose, scope, and perspective are clear and appropriate
- Scoped at appropriate level, but could have been structured better
- Scope too narrow or too broad; solved the wrong problem

Creative Alternative Generation

- Alternatives were creative and distinct; portfolio choices also available
- Sufficient project choices available
- Insufficient choices available; some choices not viable

Relevant and Reliable Information

- Information explicit and trusted; uncertainty was properly quantified
- Information is available, but some credibility concerns; uncertainty ignored
- Some key information missing

Clear Values and Tradeoffs

- Trade-offs between values for alternatives were discussed and were clear
- Decision criteria were specified
- Decision criteria were not specified

Logical and Consistent Reasoning

- Reliable analysis available for each alternative; analysis not overly complex
- Understand relationship between key uncertainties and values
- Too much group think or advocacy; poor or missing logic

Commitment to a Course of Action

- We have clarity of action and agreement on how to proceed
- A decision can be made, but the comfort level should be higher
- It is still unclear what the appropriate course of action is; we are not aligned

“Asset A”

Decision Quality survey results

	1	2	3	4	5	6	7	8	9	10	11	Average
Proper Frame	3	3	3	3	3	3	3	3	2	3	3	2.91
Creative Alternatives	3	3	3	3	3	3	3	2	3	2	1	2.64
Reliable Information	2	3	3	3	2	2	3	3	1	3	3	2.55
Values & Tradeoffs	2	3	2	2.5	3	2	2	3	2	3	2	2.41
Logical Reasoning	2	3	2	3	2.5	3	3	2	2	2	2	2.41
Clarity of Action	2	3	3	3	3	3	3	3	1	3	2	2.64
	2.3	3.0	2.7	2.9	2.8	2.7	2.8	2.7	1.8	2.7	2.2	

“Asset A” Quality Decision Process

The End