



A New Leadership Model for Biopharma Teams

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Collaborative teamwork is critical for R&D success, especially for teams pushing the limits of biopharma innovation. Using dialogue from a real project, this case study takes you backstage to see the reflective leadership skills that drive high performance.

Introduction

Successful life science leaders shift their approach from unilateral action – directing others – to mutual action – engaging with others to find a collaborative way forward.

The authors, organizational learning consultant Merle Kummer and Regulatory Affairs leader Liz Bloss, began work 15 years ago on developing leadership mastery for cross-functional drug development teams. We have not only built new practices, but discovered new ways for life science leaders to build more productive mental models.

It takes work to learn how to recognize and reframe one's own mental models. Most life science R&D leaders find it hard to imagine changing their thinking in real life. Because scientists are highly socialized to push their points, in the heat of conversation they tend to stop learning and revert to telling.

We have developed this case study so you can see what goes on in a leaders' mind in order to apply a mutual action model skillfully in a difficult meeting. Liz describes her experience, and Merle explains how the new leadership practices were applied in real time.

Case: The New Leadership Assignment

A client company had just decided to bring a promising drug candidate to the clinic, and asked me (Liz) to lead the IND preparation and submission. Senior leadership assumed they would take a regulatory path with compressed timelines. Since the accelerated regulatory path could lead to future delays, I suggested that it would be wise to look at all options.

We agreed that I would set up a teleconference meet-and-greet with the team. I had been told that the team had moved forward already, but was struggling with team dynamics. Decision-making had come to a halt. I approached the meeting with the expectation that everyone wanted the best outcome for the project. I wanted them to know I was eager to learn their ideas and build on their expertise.

Conversation

Me: Good morning this is Liz.

Paula: Good morning, I am Paula, I am the Project and Timeline Manager.

Tom: Good morning, I'm Tom. I'm representing Toxicology and am from the Nonclinical Department.

Craig: Hi this is Craig, I'm from CMC.

Mike: Hi it's Mike, I'm the Medic for this project. I think it's really a little premature for me to be at this meeting.

Me: It's so nice to speak with everyone this morning. Thank you for your introductions. Mike, thanks for being so candid; let me address your thoughts. This meeting is to provide context to the overall project, including the long-term goal of approval. We would like to define the steps and expectations along the way. It is helpful for all the team members to hear the conversation from the beginning.

Mike: This is not my first rodeo. I am fully aware of the expected goal and outcome and what I need to do.

Me: Mike, since you are here now, I think it would be helpful for you to remain part of this conversation as part of the team and hear your colleagues' input as we explore the regulatory options.

Mike: My understanding was that this team would do the accelerated submission, and I'd quickly start up the trial. I'm not sure what the process here is, my management was supposed to give more of the strategy.

Me: What about if we move forward in a stepwise fashion with the long-term goal in mind? That way we can move forward in a granular fashion and adapt quickly.

Mike: Well, I will have to see what my management wants me to do. But I could certainly help.

Me: As I said, let's talk about our proposed roles and responsibilities, leveraging each person's expertise. I had envisioned that I would lead the overall IND preparations. Tom, leveraging your subject matter expertise in the tox area, I think you could help drive the nonclinical module and the summary module of the IND.

Tom: I would be happy to be the nonclinical point person. I report into the overall Head of Nonclinical so I will have to check with her on every major milestone and decision point.

Me: Thanks for your clarification on this aspect. Perhaps she could join us for some of the milestone meetings.

Tom: I can ask her.

Me: Craig, given that you are the subject matter expert for CMC, could you please be the CMC lead and the interface to the manufacturing facility?

Craig: I will likely not be able to make every meeting, but will assign one of my CMC team members to attend those meetings that I am not able to attend. The CMC team members are empowered to make decision on my behalf although I sign-off on all key documents.

Me: Thank you Craig, it is helpful for you to clarify your role and the decision empowerment that your team members have on your behalf. I think it will be most efficient if we build in some key milestone meetings to improve decision efficiencies and streamline the document preparation and reviews.

Me: Paula, perhaps you can please develop the timelines after discussion with the team members outside of this meeting, and include their envisioned roadblocks or constraints. Then we can provide them for everyone to review prior to the next meeting. I will create the key notes and the action items for everyone to review.

Epilogue

As promised, I sent out the meeting notes and some sample content plans. The subsequent e-mails became much more friendly, once the team members realized that I was genuinely *not* interested in their jobs! Now I lead the core submission team, of which they are all members, and the dynamics are much improved.

The meeting provided a good stepping stone to future, more content-driven meetings. Remaining positive, engaged and open to everyone's input throughout the entire meeting deflected actual and potential disruptions. I wonder how it would have gone if we were all defensive?

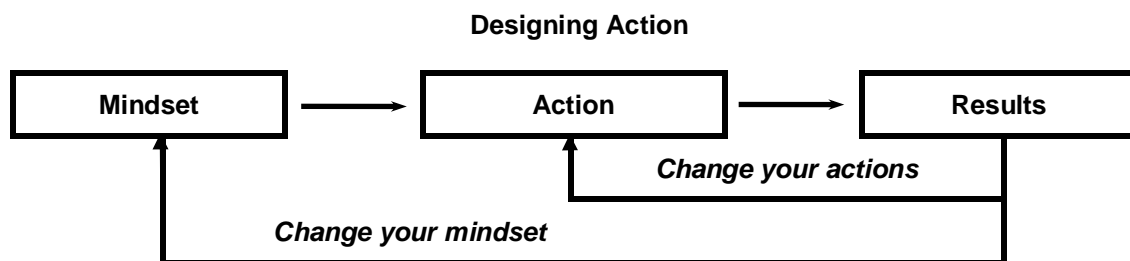
Learning New Practices: Moving from a Unilateral to a Mutual Action Model

The heart of the new leadership model is switching from a unilateral to a mutual mindset. Instead of entering conversations thinking they ought to know the answers, high-performing leaders frame conversations as opportunities to learn. They balance advocacy - explaining one's ideas - with inquiry - asking for others' thinking.

Our biopharma leadership programs introduce the skill of reframing in order to design more productive action. To learn this skill, leaders write their own conversation cases in order to analyze the impact of their current style. In the right-hand column, they show the actual dialogue, what was said and done. In the left-hand column, they note what they were thinking but not saying. We can trace back how their actions produced problematic results, and how they could change their mindset in order to produce better results.

Leaders become aware of the underlying assumptions that govern their own behavior, notice when their behavior shuts others out, and adopt more open attitudes. For example, they learn to notice when they feel defensive, and to switch to a stance of curiosity instead. They stop advocating and start inquiring, building knowledge for the whole team.

Bob Putnam of Action Design, who collaborated with Merle to develop the *Leadership for Drug Development Teams* programs, shows the learning process this way:¹



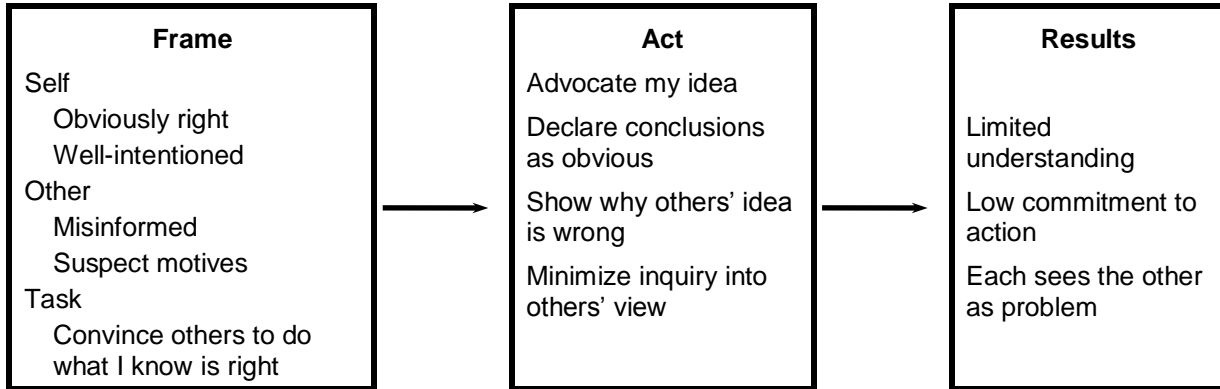
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Liz shows how a collaborative leader can switch mindsets during real team conversations. She monitors her own thinking in real time in order to design more productive actions. She has documented her immediate reactions and how she then re-framed the situation, showing how a skillful leader can shift from a unilateral to a mutual model.

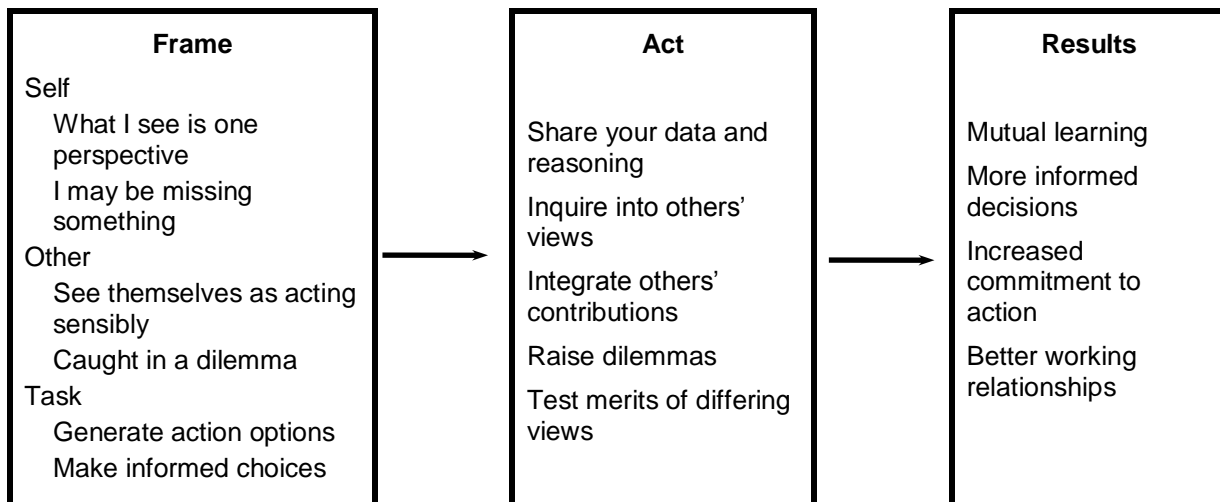
What was said	What I was thinking but not saying	
	Immediate reaction <i>Unilateral thinking</i>	Reflective Reframing <i>Mutual thinking</i>
Me: Good morning this is Liz.	<i>I really want to build a collaborative culture, but I'm not sure how the meeting participants would feel about my taking on leadership.</i>	<i>Stay focused on the goal for this meeting: identify roles and responsibilities so we can produce a high-quality submission.</i>
Paula: Good morning, I am Paula, I am the Project and Timeline Manager.		
Tom: Good morning, I'm Tom. I'm representing Toxicology and am from the Nonclinical Department.		
Craig: Hi this is Craig, I'm from CMC.		

Liz's immediate reaction is consistent with the Unilateral Action Model, first described by Argyris and Schön² in their groundbreaking work on organizational learning. They found that this model of action characterized the vast majority of interactions in organizations. They proposed an alternative model that would promote mutual learning. Action Design, founded by Argyris associates Bob Putnam, Phil McArthur, and Diana Smith, have built a practical body of knowledge for moving from unilateral to mutual action models.

Unilateral Action Model



Mutual Action Model



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Liz's immediate framing of the situation maps to the Unilateral model:

I really want to build a collaborative culture, but I'm not sure how the meeting participants would feel about my taking on leadership.

	Liz's initial frame	Unilateral Action Model Frame
Self	My goal of building a collaborative culture is what the team needs.	Obviously right Well-intentioned
Others	They're wary of me but they haven't been able to lead this themselves.	Misinformed Suspect motives
Task	Take leadership and build a collaborative culture.	Convince others to do what I know is right

Liz is able to reflect and reframe from a unilateral to a mutual mindset:

Stay focused on the goal for this meeting: identify roles and responsibilities so we can produce a high-quality submission.

Notice that Liz frames the task not as *assigning* but as *identifying* roles and responsibilities. Instead of following directions, the team will seek and find a pathway together.

	Liz's new frame	Mutual Action Model Frame
Self	Step back from my own concern - taking leadership - and look at the requirements of the project.	What I see is one perspective. I may be missing something
Others	Roles and responsibilities have not been clear.	See themselves as acting sensibly Caught in a dilemma
Task	Jointly identify roles that can produce high-quality submission.	Generate action options Make informed choices

The meeting continued.

	Immediate reaction	Reflective Reframing
Mike: Hi it's Mike, I'm the Medic for this project. I think it's really a little premature for me to be at this meeting.	<i>He's got a chip on his shoulder.</i>	<i>Thinking about his attitude here is not helpful. To reach our goal, we need to understand individuals' perceived apprehensions.</i>

Mike's remark triggered a familiar suspicion about MDs for Liz: she'd argued with too many medics over missed deadlines and misunderstood regulations. In this conversation, by reflecting on her reaction, she remembered that dwelling on negative opinions had wasted her own time and energy.

She realized that addressing his concerns would be important for working together, and acted differently. Knowing how her actions could impact others' behavior, Liz noticed her hackles rising and consciously reframed from her real apprehension to her no less real enthusiasm. Instead of refuting him, she acknowledged his concern and was transparent about her own thinking.

Consciously using the mutual model, she continued:

Me: It's so nice to speak with everyone this morning. Thank you for your introductions.	<i>Still a little apprehensive and noticed their nervousness.</i>	<i>I'm enthusiastic about this team and want them to know that.</i>
Mike, thanks for being so candid; let me address your thoughts. This meeting is to provide context to the overall project, including the long-term goal of approval. We would like to define the steps and expectations along the way. It is helpful for all the team members to hear the conversation from the beginning.		<i>Mike is candid and I can leverage that. Keep my voice calm and state my real intention directly. My approach can affect the outcome.</i>
Mike: This is not my first rodeo. I am fully aware of the expected goal and outcome and what I need to do.	<i>Cutting and derogatory, I detect attitude.</i>	<i>Don't let the negative behavior of others distract you from the purpose of the meeting.</i>

Mike responded unpleasantly, but she didn't let her old routine take over.

	Immediate reaction	Reflective Reframing
Me: Mike, since you are here now, I think it would be helpful for you to remain part of this conversation as part of the team and hear your colleagues' input as we explore the regulatory options.	<i>As I listened, this isn't directed toward me personally. He doesn't know me at all.</i>	<i>Negativity, even in my voice, is not helpful here.</i>

Liz's immediate reaction became less unilateral as she listened more. Understanding Mike's perspective made it easier to frame him with a mutual model. Mike began to respond differently.

Mike: My understanding was that this team would do the accelerated submission, and I'd quickly start up the trial. I'm not sure what the process here is, my management was supposed to give more of the strategy.	<i>Senior management could likely communicate a bit better to the team.</i>	<i>I can understand his concern.</i>
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In response to her genuine interest in his participation, Mike provided his view. This put more information about the project history on the table.

She saw the dilemma he faced, and, using the Mutual Action Model, generated an action option that addressed Mike's concerns.

Me: What about if we move forward in a stepwise fashion with the long-term goal in mind? That way we can move forward in a granular fashion and adapt quickly.	<i>I'm pretty sure acceleration won't work, but we haven't looked at this together.</i>	<i>I can be flexible. If I adjust my plan, it will give us time to build shared understanding of the path forward.</i>
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Mike: Well, I will have to see what my management wants me to do. But I could certainly help.	<i>Tone is still curt.</i>	<i>Focus on what he's saying, not how he is saying it. He stopped pushing back, and is considering my idea.</i>
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By moving away from her original plan, Liz opened up a path that would accommodate either regulatory option. This enabled Mike to stop pushing against Liz.

This whole segment of the meeting shows the results that the mutual action model can produce. Instead of each seeing the other as a problem, they were on their way to reaching shared commitment to action.

Mutual Model	Liz's action
Share your data	Describe what senior leadership had asked her to do.
Share your reasoning	Explain her approach to the project: establish the context so that the whole team can define the steps to deliver the submission.
Integrate others' contributions	Speak to Mike's thoughts.
Inquire into others' views	Let Mike know how helpful his participation will be for the team.

Task:

Generate action options
Make informed choices

Suggest a way that would enable the team to learn about the merits of each regulatory strategy without delaying the preparatory work.

With a similarly open mind, Liz went on to identify roles and responsibilities with the rest of the team.

	Immediate reaction	Reflective Reframing
<p>Me: As I said, let's talk about our proposed roles and responsibilities, leveraging each person's expertise. I had envisioned that I would lead the overall IND preparations.</p> <p>Tom, leveraging your subject matter expertise in the tox area, I think you could help drive the nonclinical module and the summary module of the IND.</p>	<p><i>Listening to the team members concerns is key.</i></p>	<p><i>Remain positive and open to their insights and opinions.</i></p> <p><i>Propose my ideas for their roles and ask for their reactions.</i></p>
<p>Tom: I would be happy to be the nonclinical point person. I report into the overall Head of Nonclinical so I will have to check with her on every major milestone and decision point.</p>	<p><i>Finally, someone who is a little kinder. But his function head likely is a micromanager.</i></p>	<p><i>Look at this from Tom's perspective. This is the way he needs to operate within his functional organization.</i></p>
<p>Me: Thanks for your clarification on this aspect. Perhaps she could join us for some of the milestone meetings.</p>	<p><i>Don't make things harder for him.</i></p>	<p><i>We can benefit from her knowledge and streamline the process.</i></p>
<p>Tom: I can ask her.</p>		
<p>Me: Craig, given that you are the subject matter expert for CMC, could you please be the CMC lead and the interface to the manufacturing facility?</p>		
<p>Craig: I will likely not be able to make every meeting, but will assign one of my CMC team members to attend those meetings that I am not able to attend. The CMC team members are empowered to make decision on my behalf although I sign-off on all key documents.</p>	<p><i>A little better but still cumbersome. Multiple sign-offs waste time.</i></p>	<p><i>It's hard for function heads to make sure things go well.</i></p>
<p>Me: Thank you Craig, it is helpful for you to clarify your role and the decision empowerment that your team members have on your behalf. I think it will be most efficient if we build in some key milestone meetings to improve decision efficiencies and streamline the document preparation and reviews.</p>	<p><i>Reinforce candidness – let him know that I encourage transparency.</i></p>	<p><i>Engage him in improving the process. He's in a position to drive change.</i></p>

Immediate reaction

Reflective Reframing

Me: Paula, perhaps you can please develop the timelines after discussion with the team members outside of this meeting, and include their envisioned roadblocks or constraints. Then we can provide them for everyone to review prior to the next meeting. I will create the key notes and the action items for everyone to review.

I'd better control all the next steps.

If I do that, I'm disempowering the team. Let me ask Paula to be collaborative.

I will draft the notes and action items and then send them for review to show that I'm committed to hearing what they said.

Starting with self-awareness, the reflective leader diagnoses difficult interpersonal dynamics, reframes tough situations, and moves the conversation in productive directions. This thoughtful attention to team interaction builds strong working relationships. We hope that this case demonstrates reflective leadership practices underlying the collaborative teamwork that is critical for R&D success.

¹ Putnam RW, [Double-Loop Learning](#), Chapter in The Sage Encyclopedia of Action Research. David Coughlin and Mary Brydon-Miller (eds.). Sage Press, 2014

² Argyris and Schön, *Organizational Learning*, Addison-Wesley 1978; see also Argyris, Putnam and Smith [Action Science](#), Jossey-Bass 1985.