

A StAR is Born: AstraZeneca/Quintiles Collaborating for Success

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ABSTRACT

AstraZeneca and Quintiles have entered into a strategic Early Clinical Development analysis and reporting collaboration, the **St**atistical **A**nalysis and **R**eporting (StAR) alliance, breaking down the traditional hierarchical Pharma/CRO relationship and placing both companies firmly on the same platform with an integrated operating model and shared visions and successes.

The poster will expand on this innovative collaboration model by addressing the following key topics:

Building the right collaborative culture; highlighting the successes, challenges and lessons learnt in integrating teams, how encouraging decision making and accountability can strengthen relationships.

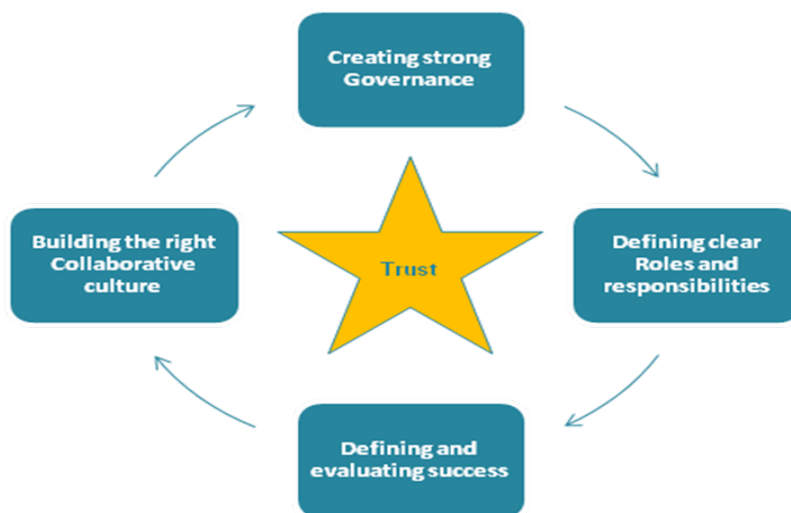
Focus on strong Governance within the collaboration, to aid support, direction and align visions, goals and objectives across the two companies.

Define clear roles, responsibilities and touchpoints between the two companies encouraging expert to expert communication and collaboratively in defining process, documentation and training support.

How defining and evaluating success throughout the evolving processes are important but being agile and flexible is key.

INTRODUCTION

Agreements and collaborations between Pharma and CRO's are commonplace today within R&D. When the StAR alliance for the delivery of **S**tatistical **A**nalysis and **R**eporting of Early Clinical Development studies was first set up, we wanted to build a strong alliance between AstraZeneca and Quintiles right from the start. We focused on trust and collaboration to ensure the two companies shared the same vision and built the right culture to successfully deliver studies within AstraZeneca's early clinical portfolio. Our companies have a long and successful alliance history, including the newly formed **M**odel for **A**nalysis and **R**eporting **S**ynergies (MARS) alliance within the later phase portfolio. Within this paper we will outline four key areas that we feel show the innovative way we set up and continue to manage our StAR alliance.



STRONG GOVERNANCE

A strong, cohesive governance organization is essential to any collaboration. Within the StAR alliance we identified key colleagues to join a kick-off meeting face to face. We had representation from both companies from operational, alliance and senior management levels. Discussions, debates and opinions centered on the vision of the collaboration, the expectations and requirements of each organization, and the initial strategies for turning the vision into reality. Previous agreements and relationships were discussed and lessons learnt taken into account during the construction of the collaboration.

Discussions centered around aligning the vision of the collaboration and focusing our objectives on what we wanted to achieve together. We embraced the true reasons behind our relationship; the primary objective of building a collaboration which helps makes better drug decisions for patients. This helped drive our relationship to be an agile, innovative and high performing collaboration which puts science and patients at the heart of everything we do, truly bringing people and knowledge together to help make a meaningful difference to patient health.

A governance charter was put in place following this successful kick-off meeting, identifying two StAR alliance specific governance levels; an operational steering committee (OSC) to provide operational guidance to study teams and an executive steering committee (ESC) to set the vision, strategy and direction of the collaboration. Roles and responsibilities of each governance level were clearly highlighted, and a strong link was created between the governance levels.

The charter included a communication and escalation path, ensuring that achievement and successes were identified clearly and shared. Challenges and issues were highlighted quickly, and addressed in a timely manner at the appropriate level. Interactions and touch-points were carefully considered and governance members were strategically selected to ensure appropriate communication and influence within the broader enterprise, resulting in channels to senior leadership being opened to allow clear visibility of the collaboration. Both companies were fully

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vested in making the collaboration a success and achieving our goals.

Additionally, a stakeholder map and communication plan was put in place to ensure all stakeholders are receiving the appropriate level of information in a timely manner.

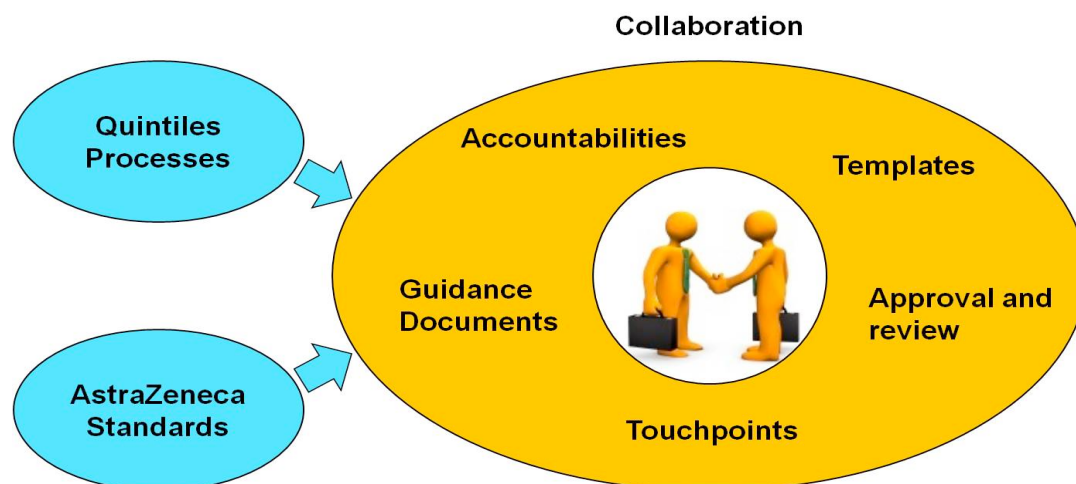
Regular governance face to face meetings were suggested, planned and implemented, ensuring that despite the global nature of the collaboration, key successes, achievements and challenges could be shared. Meetings are focused on the implementation and performance of the collaboration, allowing for clear, unbiased assessment of issues and challenges with associated collaborative mitigation strategies. This unified governance approach further strengthened and solidified the focus on the objectives of the collaboration.

Governance of the model places emphasis on successes and achievements and not solely challenges and issues. This created a support base for study teams and for each organization. Solution-orientated discussions were encouraged, helping drive the collaboration forward. Challenging topics such as budget, resource capacity, pipeline visibility, and other issues affecting the collaboration could be discussed openly and joint solutions implemented.

This governance organization ensures levels of communication and support are clear, and helps ensure study teams are provided with all the required tools to turn the collaboration vision into reality. We recognize that there will be rocks in the water, and how we both proactively and retroactively deal with these challenges and issues as a governance organization will define our collaboration and ensure we successfully navigate these rocks.

DEFINING CLEAR ROLES AND RESPONSIBILITIES

The model has been designed to remove duplication of roles and responsibilities at both companies, allowing simplification of the model. This was done by defining clear accountabilities at Quintiles and AstraZeneca, allowing control of analysis and reporting study activities to sit firmly within Quintiles. Clear touch points were proposed for AstraZeneca Project teams to review and approve with a 'light touch' approach to the study work. AstraZeneca personnel are there to support the model as expert points of contacts. The design of work is carried out using Quintiles processes and AstraZeneca's standards, allowing Quintiles team members to understand clear expectations of what is required from a standards perspective, while AstraZeneca team members can expect consistent and familiar outputs. This allows simplification of understanding and ensures consistency within studies.



We have developed one streamlined and clear training session for all new members at both Quintiles and AstraZeneca. This allows everyone to understand the same message, values and accountabilities, but also helps everyone integrate into one team quickly. In addition to the training we have developed together several one page guidance documents, FAQ sheet and templates, allowing us to add clarity to the different stages of the study development; this is a continual process lead by the OSC with involvement of all members of the alliance.

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To further the collaborative work we do and help build on open communication we have been able to hold cross functional meetings and training sessions to share knowledge and experience on topics that can help benefit the work we do in early clinical development.

To make sure that we continue to share knowledge consistently and that is always accessible, finding the right management/repository tool was important, we have chosen to use the cloud based management sharing tool called BOX, this allows easy access and management to all team members and prevents the duplication of data and possible confusion when information is held at each company.

As part governance model the OSC was set up to help with the management of the activities within the model, regular meetings allow us to collaboratively review progress, make changes and discuss new ways to solve challenges. All communication to the teams within the alliance are driven from this group, but we also act as champions for the alliance on the office floor for face to face contact with the teams, helping with questions or concerns. Emphasis is placed on continuous improvements and study teams are encouraged to show initiative and innovation to further enhance processes and interactions.

DEFINING AND EVALUATING SUCCESS

Success can be defined in many ways, and while each company has their own success objectives, identifying the success of the collaboration and aligning both companies to that success has proved invaluable. Formal service level agreements (SLAs) and key performance indicators (KPIs) were put in place, although emphasis was placed on informal predictors also, notably what study teams think, how they interact, and what interaction criteria are important to them.

A formal health survey was put in place to assess how colleagues from both organizations perceive the model, allowing for an unbiased assessment of the state of the model. Responses were assessed and a comprehensive action plan was developed, communicated and implemented. Both positive and negative messages were shared across the collaboration, with joint decisions, accountability and responsibility for corrective actions and next steps.

A formal metrics collection and presentation mechanism was developed, including the creation of a standard scorecard shared at governance meetings. In addition, focus is placed on intangible measures that define the perceived success, for example whether study team leaders feel they are receiving the appropriate responsiveness to requests, and whether the required resource agility and flexibility to handle unplanned requests has been shown.

In situations when formal measures were hindering and blocking successful delivery, the formal SLAs/KPIs were reassessed and swift corrective actions were implemented. This re-alignment of the formal SLAs and KPIs helped drive the collaboration towards the joint objectives and goals, and accounts for key innovation topics.

The visibility of successes and achievement of the collaboration was emphasized, with positive messages, key milestones and examples of embodiment of the collaboration highlighted on a constant basis and shared with senior leaders.

One of the next steps for the governance organization is implementing a mechanism for recognizing colleagues across organizations for outstanding contribution. Both Quintiles and AstraZeneca have reward systems for recognizing colleagues, and extending this system and creating a culture of recognition across organizations will further enhance the principles of this collaboration. Coupled to this is assessing individual performance across organizations. Again both organizations have a formal performance review system, and requesting feedback across organizations will provide insights not only into the individual performance but also general alignment to the collaboration objectives.

A key focus of this collaboration is simplicity, and continuous process improvement plays a key role. Suggestions, insights, and comments are collected on an ongoing basis and process improvement initiatives are put in place. Not all improvements are instant, but together the collaboration will reach its vision.

RIGHT COLLABORATIVE CULTURE

Creating the right collaborative culture is key to the success of the StAR alliance. We feel we have gone a long way into breaking down the traditional barriers that can often hinder successful vendor relationships. By aligning our goals right from the start and building trust within the alliance, as well as maintaining a healthy relationship through the alliance.

Having a strong ESC and OSC with an open and honest approach allows easy transfer of the vision to the teams. Listening to concerns and challenges, responding with positive solutions and not focusing on failures, helps us successfully deliver on work and also plan for future work.

Key messages are reinforced from our ESC through to our OSC and onto our study teams.

We are fully committed to building and maintaining the right collaborative culture within the alliance, we believe by setting up and maintaining the following areas we can continue to be successful and weather any potential storms in the future.



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CONCLUSION

Any successful collaboration has challenges to overcome and the StAR alliance is no different. One of the key challenges continues to be bridging the gap across organizations within the study teams, breaking the traditional hierarchical Pharma/CRO relationship and bringing colleagues together under one study team for a shared objective, irrespective of organization. We believe we're overcoming this challenge by clearly communicating our StAR alliance vision, objectives and strategies, highlighting roles and responsibilities, and empowering study team members to make decisions. Additionally, colleagues are continuously building trust through, amongst others, reliable and quality interactions, and through constant feedback and communication, cohesion and collaboration is carefully monitored.

Success within the StAR alliance is viewed as a series of achievements. These include the creation of our operational handbook and guidance documents, cross-organizational discussion sessions, health survey and associated action plan, sharing of our collaboration through the PhUSE conference and study milestones. As we move into our second year of the alliance we can reflect on some of the positive results this alliance has achieved; kick off meetings on all projects, statistical analysis plans finalized and many others in final drafts, flexibility in the response and production of outputs for safety review boards and the deliverable of our first study interim analysis. While this collaboration remains in the early stages, these achievements provide the ongoing evidence that our collaboration is on the road to success.

Within the StAR alliance we believe our shared vision and objectives, along with our governance structure, process guidance and operational support, places AstraZeneca and Quintiles firmly on the same platform and drives our shared successes.

ACKNOWLEDGMENTS

We'd like to acknowledge first and foremost our study teams, including colleagues from both AstraZeneca and Quintiles, for their continued dedication and commitment to our collaborative vision. They have embraced our objectives and are successfully turning our vision into reality.

Additionally acknowledgements include our OSC and ESC team members, and senior leadership team for their continued guidance and support.

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