

A StAR is Born: AstraZeneca and Quintiles Collaborating for Success

PP23

Alison Dobson, AstraZeneca, Alex Brink, Quintiles



Introduction

AstraZeneca and Quintiles have entered into a strategic Early Clinical Development **Statistical Analysis and Reporting (StAR) Alliance**. When the StAR Alliance was first set up, we wanted to focus on building a strong alliance 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. The poster focuses on 4 areas; creating strong governance, defining clear roles and responsibilities, building the right collaborative culture and defining and evaluating success.

Strong Governance

Within the StAR alliance we identified key colleagues to join a kick-off meeting face to face, with representation from operational, alliance and senior management levels. Discussions centered on the vision and the initial strategies for turning the vision into reality. This helped drive our collaboration to be an agile and innovative 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.

Two StAR alliance specific governance levels were created with members from each company; 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 relationship.

Governance of the model places emphasis on successes and achievements and not solely challenges and issues, creating a support base for study teams and for each organization. Challenging topics such as budget, resource capacity, pipeline visibility, and other issues affecting the relationship could be discussed openly and joint solutions implemented.

We recognize that there will be rocks in the water, and how we deal with these challenges and issues as a governance organization will define our collaboration and ensure we successfully navigate these rocks.

Clear Roles and Responsibilities

The model has been designed to remove duplication of roles and responsibilities, allowing simplification of the model. This was done by defining clear accountabilities at Quintiles and AstraZeneca, allowing control of the analysis and reporting study activities to sit firmly within Quintiles.

Clear touch points were defined for AstraZeneca Project teams to assist in review and approval with a focus on 'light touch'. The AstraZeneca teams 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, this allows clear understanding and accountability but also helps keep consistency within AstraZeneca studies.

We focus on delivering a single streamlined training session given to everyone as they join the team, this allows the same message, knowledge and accountabilities to be clearly transferred. One page guidance documents, FAQ and templates have been designed collaboratively within the OSC as a result of feedback and continuous improvement.

The Right Collaborative Culture

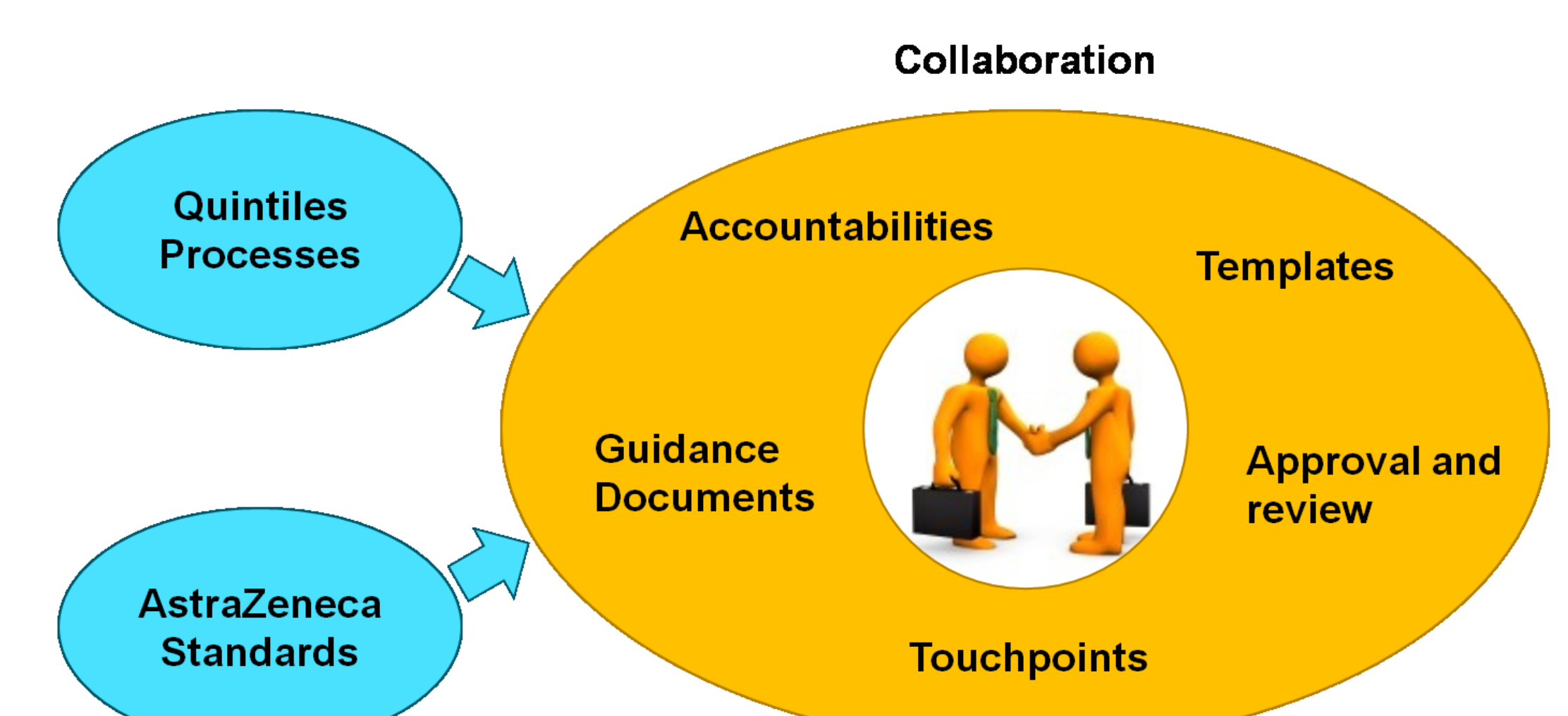
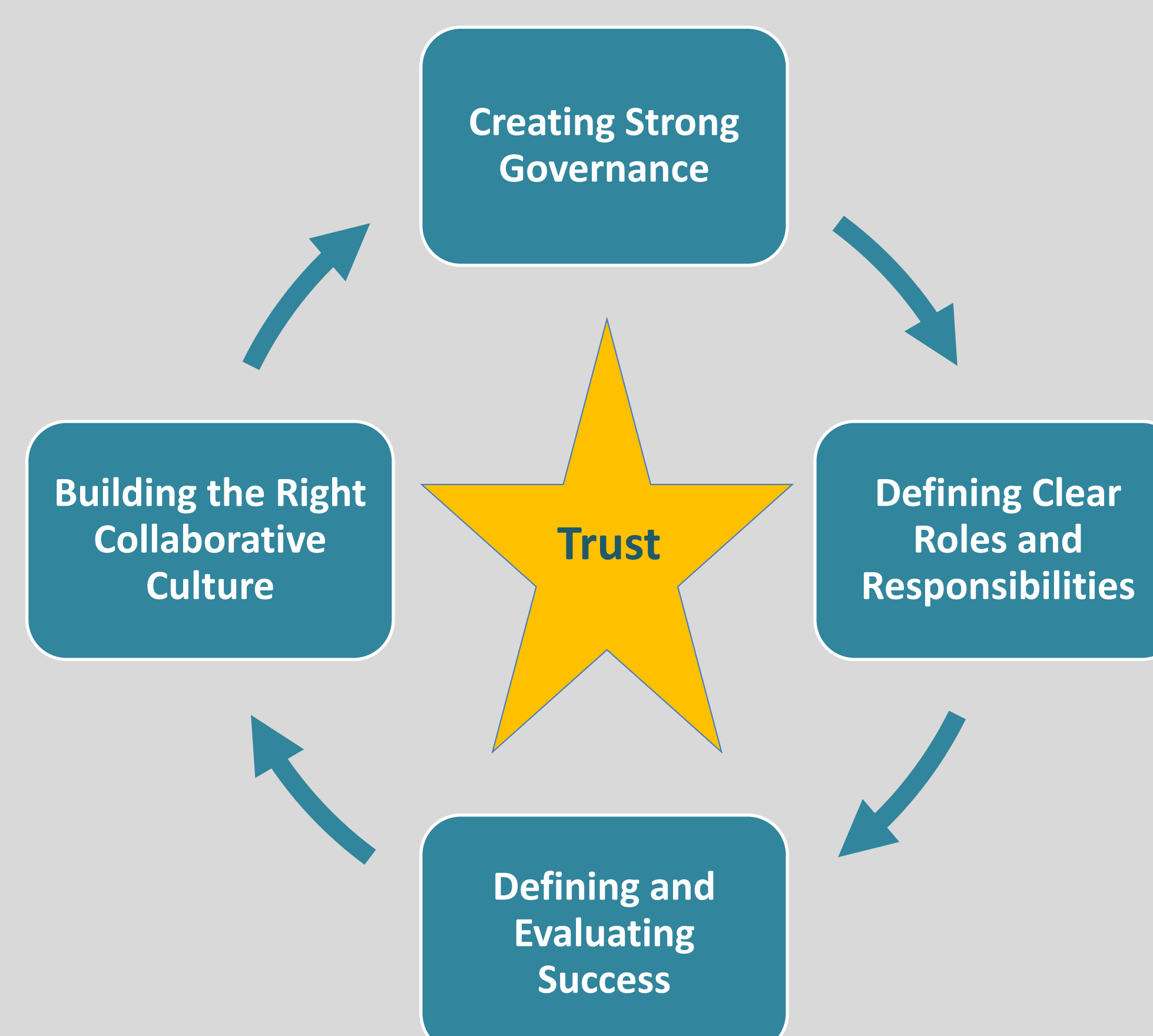
Creating the right collaborative culture is key to the success of the StAR alliance. We feel we have gone a long way into breaking down the traditional barriers that can often hinder successful vendor relationships. We aligned our goals right from the start, building trust within the alliance.

Having a strong ESC and OSC with an open and honest approach allows easy transfer of the vision right through to the teams.

To maintain the collaborative culture requires us to always look for continuous improvements where needed. We encourage the teams to reach out to the OSC members for feedback or advice, as an open door policy.

Joint knowledge sharing sessions have been set up to further collaboration, allowing solution-orientated discussions.

We are fully committed to maintain the right collaborative culture within the alliance, below is what we feel is key to our continued success.



Defining and Evaluating Success

Identifying the success of the collaboration and aligning both parties 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 the success of the deliverables.

A formal health survey was put in place to assess how colleagues from both organizations perceive the model, along with a formal metrics collection and presentation mechanism. In situations when formal measures were hindering and blocking successful delivery, the formal SLAs/KPIs were reassessed and swift corrective actions were implemented.

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.

Summary and 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 the organizations, breaking the traditional hierarchical Pharma/CRO relationship. We believe we're overcoming this challenge by clearly communicating our StAR alliance vision, objectives and strategies; creating the right culture to work within, defining clear roles and responsibilities, and empowering study team members to make decisions.

As we move into our second year of the alliance we can reflect on some of the positive results we have achieved; kick off meetings on all projects, Statistical analysis plans finalized and many others in final drafts, flexibility in response and production of outputs for safety review boards and the delivery 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.

