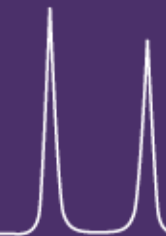


Evolutionary Outsourcing Model: Delivering Solutions through Partnership

Tammy Harter and Tony Parry

Clinical Bioanalysis Alliance
(CBioA)

Clinical Bioanalysis Alliance | (CBioA)



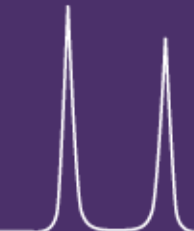
Pre Alliance Years

- History
- Drivers for change
- The “old” model

Clinical Bioanalytical Alliance

- The early years
- Implementation
 - Foundational /Project Activities and people
- Business as usual
- Maturing Alliance

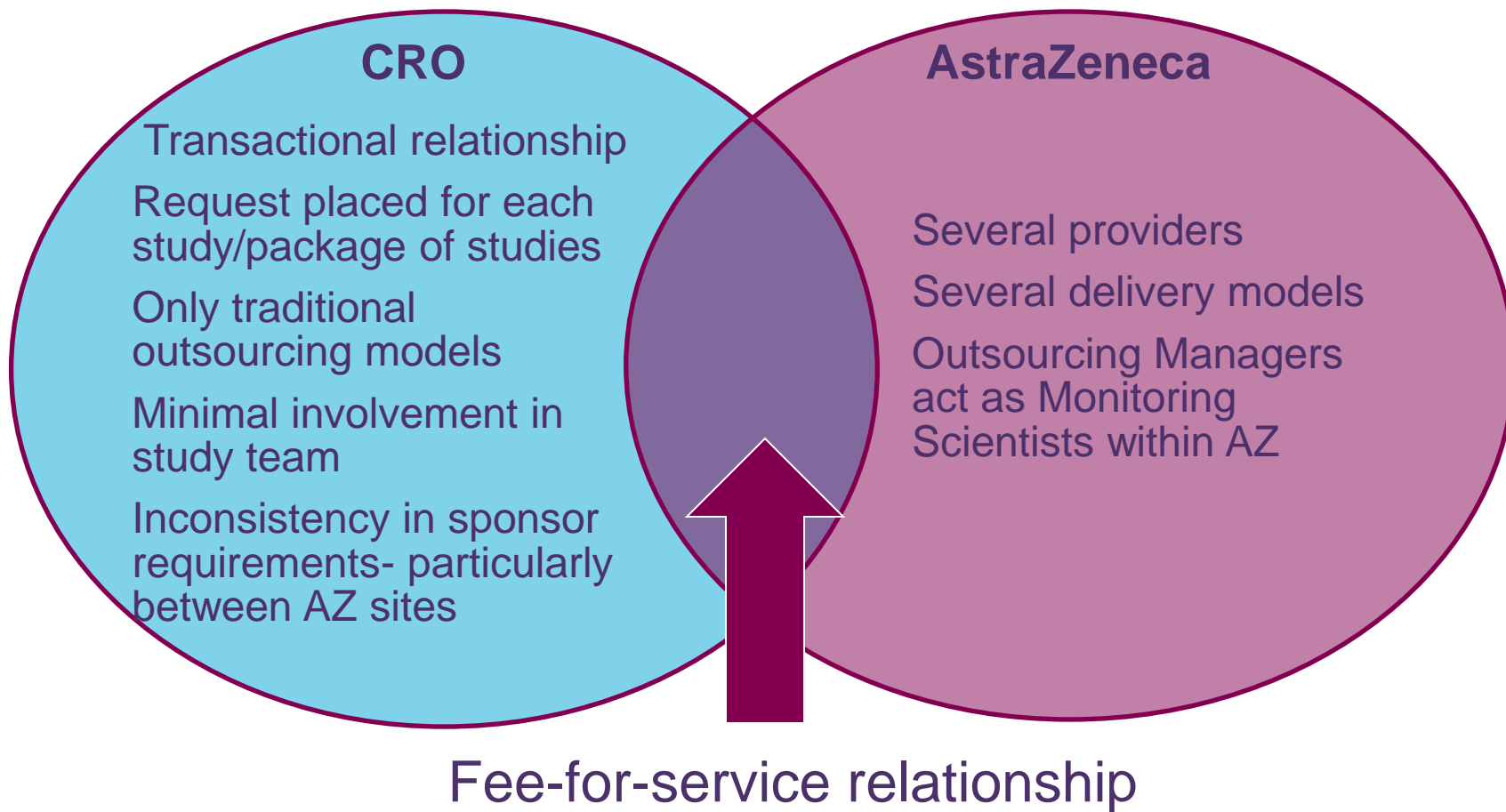
History and drivers for change at AZ



- ❑ Pre 2007
 - ❑ Six sites across 2 continents and 3 countries
 - ❑ Multiple outsourcing models - vast number of providers (some global, other local)
 - ❑ Fee for service
- ❑ 2007 - 2010
 - ❑ First moves to creating a unified outsourcing model
 - ❑ Category Management, Preferred Providers, Governance process
 - ❑ Global Discipline lead with Outsourcing Leads at each site
 - ❑ Charnwood, Lund, Sodertälje, Wilmington Bioanalytical labs closed

- ❑ Change drivers:
 - ❑ Patent cliff
 - ❑ Increase cost of R&D and decreasing Return On Investment
 - ❑ Global recession
- ❑ Clinical response to challenging environment
 - ❑ Reduce fixed cost
 - ❑ Full outsourcing of small molecule clinical bioanalysis
 - ❑ Centralise outsourcing – Alliance model

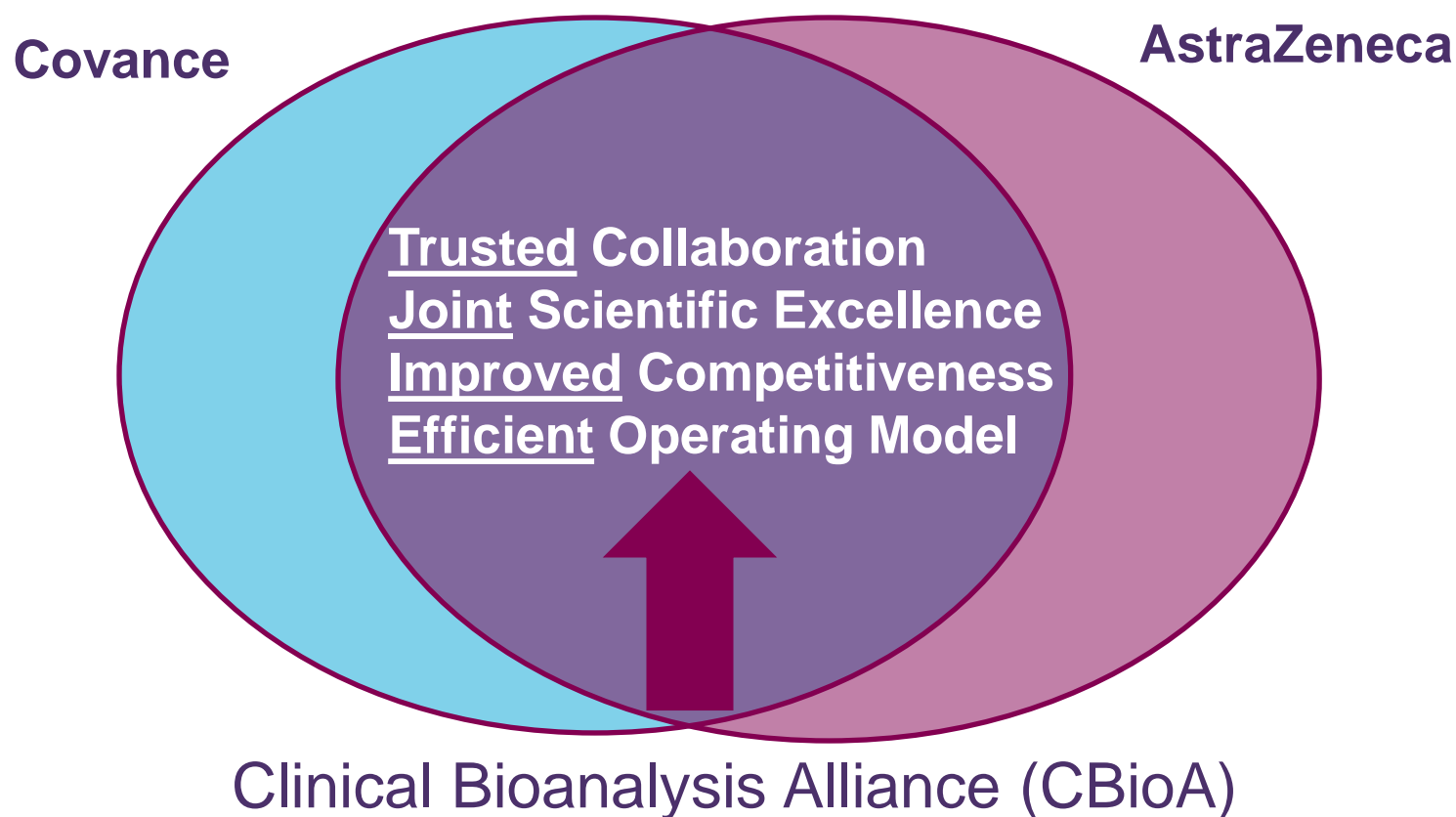
How bioanalysis data was delivered in the “old” model



The new 'Alliance' model

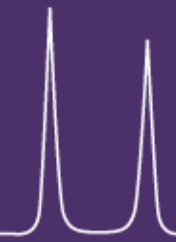


A strategic alliance between AstraZeneca and Covance to provide small molecule clinical bioanalysis globally



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The Early CBioA Years



Foundational Activities

- ❑ Structure
- ❑ Roles and Responsibilities

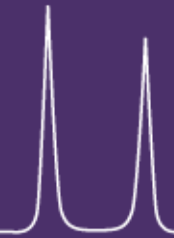
Project Activities

- ❑ Implementation/Method transfers
- ❑ Alignment of processes

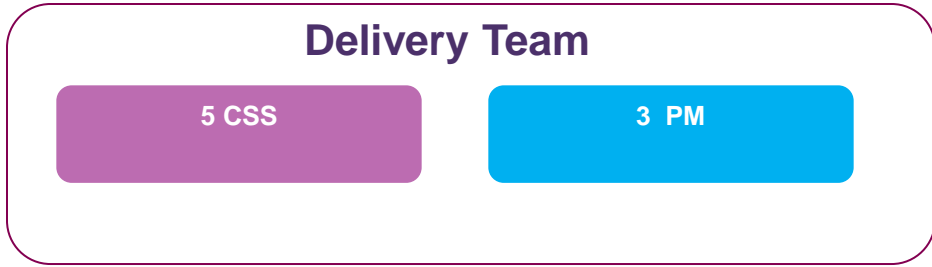
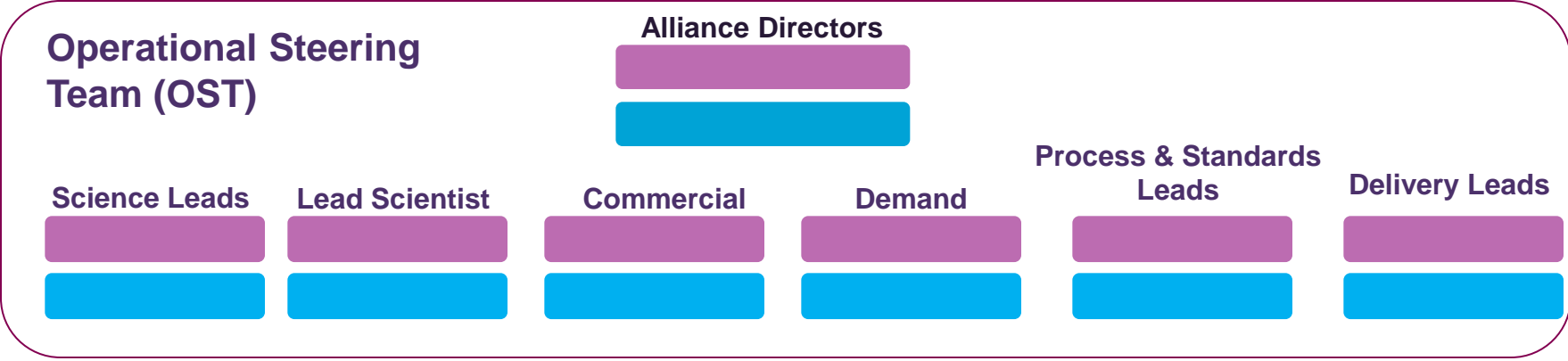
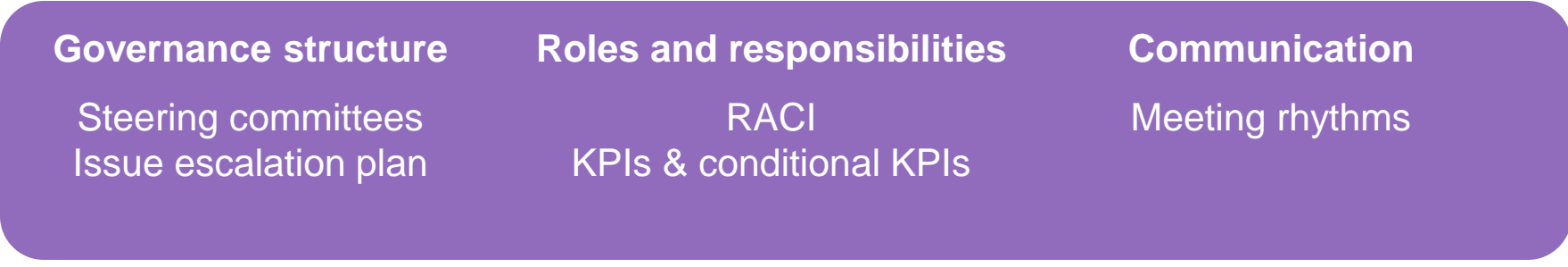
People

- ❑ Selection
- ❑ Training & Education

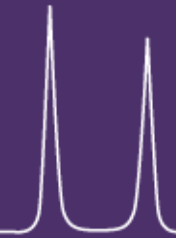
Foundation of Alliance - Structure and Processes



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Delivery team - Core interfacing roles and responsibilities of PM and CSS



Covance Program Manager (PM)

- Embedded within clinical study team
- Coordinate and monitor at **study level**
- Ensure regulatory and scientific strategies
- Ensure compliance
- Represent AZ within Covance

AZ Clinical Sample Scientist (CSS)

- Consult with AZ PK Scientists
- Coordinate and monitor at **project level**
- Oversee standards
- Represent Covance within AZ



Implementation/Method transfers

Controlled transfer of ~50 methods

Timing dependent on project status and next studies

Site selection dependent on study location and resources

Alignment of processes

Within AZ

Within Covance

Between AZ and Covance

Between Covance and other AZ partners



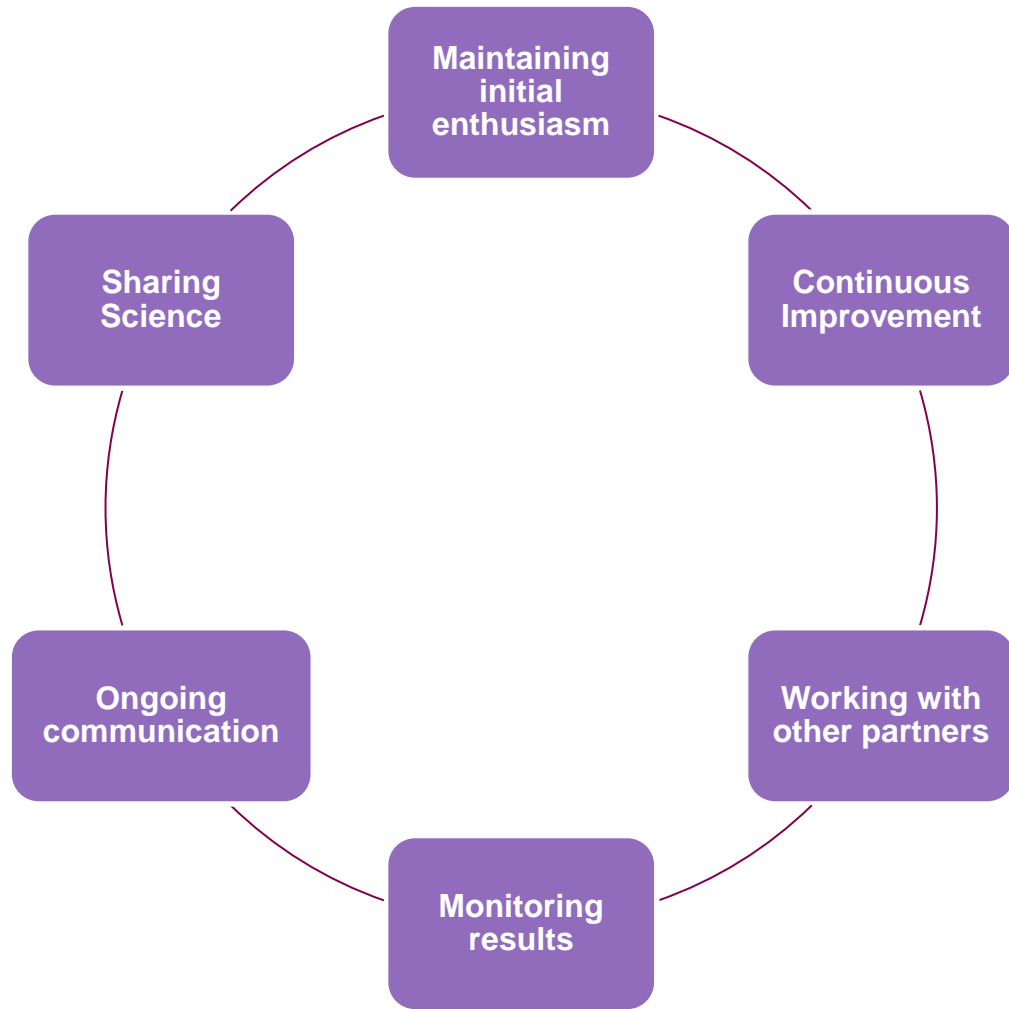
Training and Education

Alliance members
Project and study teams

Communication

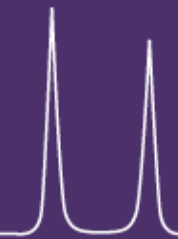
Change agents
Roadshow
Communication team

Business as usual



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Case study 1: Scientific experience shared – inhalation compounds



Situation :AZ bioanalytical facility and process developed and honed over a number of years to handle our Inhalation portfolio to specifically manage:

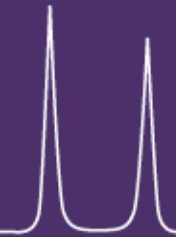
- Small molecules, designed to fly and stick
- Requirements for high sensitivity assays
- High potential for contamination

How did the alliance model make a difference?

- PM invited to AZ site to share their extensive knowledge and experience
 - Facilities and equipment
 - Preparation of reagents, solutions, spiked samples, method extraction, precautions
 - Use of Personnel Protective Equipment, handling of waste and decontamination
 - Remedies if contamination observed

Outcome: PM returned and put together an education package, detailing principles and best practices which was rolled out to all sites and applied across other therapy areas

Case study 2: Leveraging the Alliance globally – value of regional labs



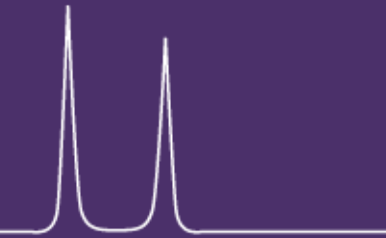
Situation: Clinical bioanalysis to support large global Phase III studies, requiring use of multiple bioanalytical labs across the globe

How did the alliance model make a difference?

- ❑ Global analysis coordinated by PM for different regional BioA sites (incl. China)
- ❑ PM active member of internally (AZ) and externally (CRO) led study teams
- ❑ Long standing trusting relationship allowed issue resolution by PM directly
 - ❑ Seamless transfer of assays and cross-validations between Covance sites
 - ❑ Use regional knowledge to facilitate importation of PK samples to China
- ❑ Processes in place to provide data rapidly for different submissions, within shortened timelines

Outcome: Analysis performed at multiple bioanalytical labs within single clinical studies; multiple data deadlines achieved across the globe

Case study 3: Open communication and appropriate use of issue resolution



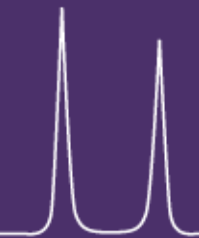
Situation: Multiple, difficult and complex methods required for a rapidly accelerated program

How did the alliance model make a difference?

- ❑ PM engaged with AZ BioA teams to learn from pre-clinical assay development and select appropriate animal ex-vivo samples for method development of clinical method
- ❑ Close collaboration between PM and AZ PK Scientists regarding predicted concentration range and requirements for additional matrices
- ❑ PM led the complex methodology required for different matrices
- ❑ Flexibility of team to assist the rapid progression of accelerated timelines
- ❑ Sharing expertise with AZ and other partners to help resolve method issues for non-CBioA supported studies
- ❑ Alliance championed excellent, open and honest communication
- ❑ Study team work directly with PM for issue resolution

Outcome: Multiple validated methods used to successfully support rapidly accelerated program

Case study 4: Supporting AZ outside the scope of the Alliance



Situation: AZ pre-clinical provider having issues in developing and validating a pre-clinical assay for which a clinical assay had already been established

How did the alliance model make a difference?

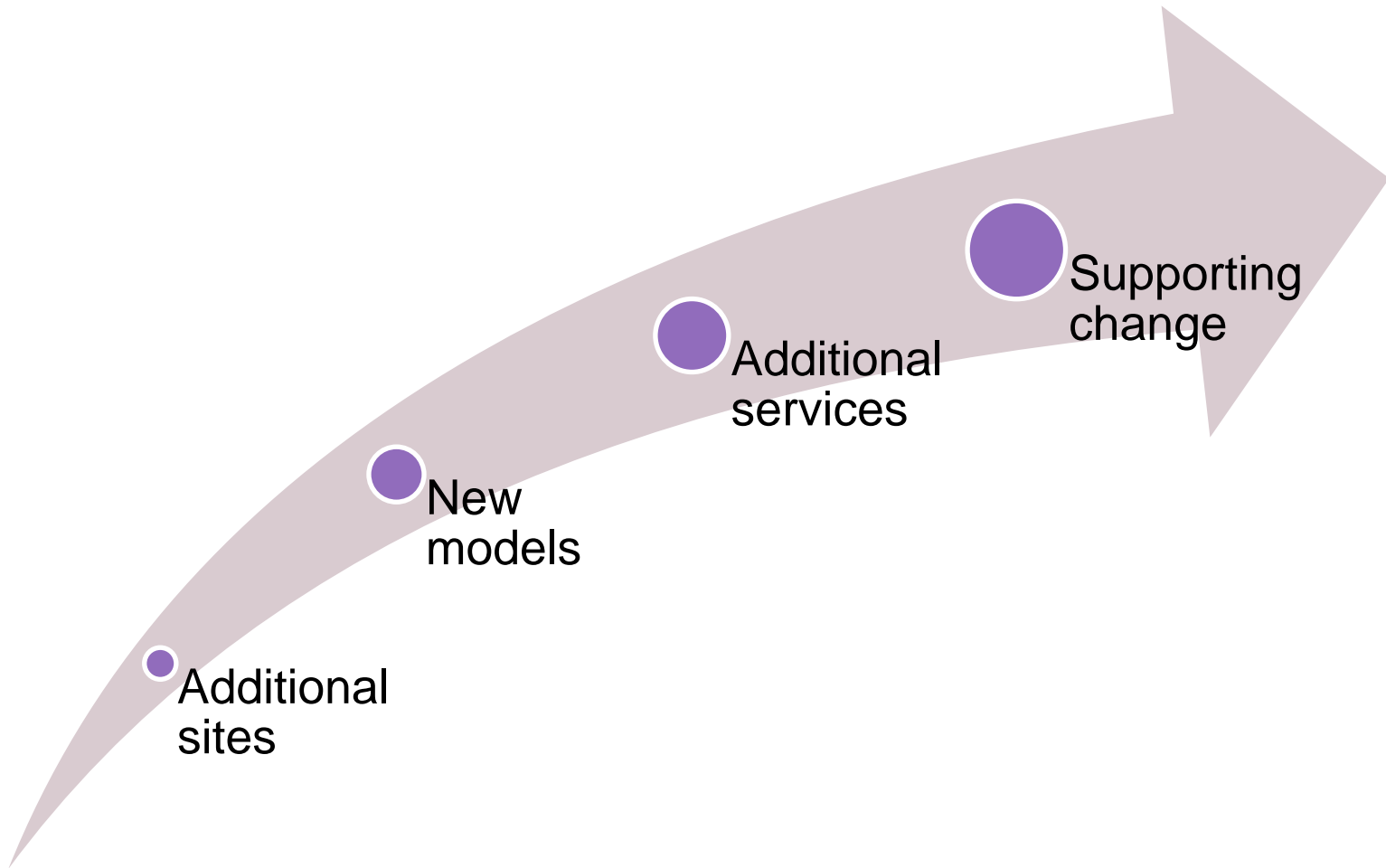
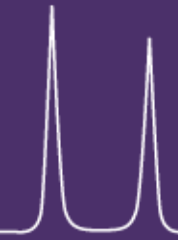
- ❑ Unique relationship between Covance and AZ through the Alliance led to pre-clinical DMPK project representative requesting a joint meeting to be attended by scientists from AZ, Covance and AZs partner.

Outcome:

- ❑ Covance scientists able to share data and experience with other scientists directly and agree joint recommendations
- ❑ Recommendations implemented and issues were resolved ensuring timely bioanalysis support to pivotal toxicity studies.



- ❑ Efficiency gains
 - ❑ Covance decides on location of assays
 - ❑ PMs embedded in the study team
 - ❑ Consistent end-to end process understood by study teams
 - ❑ Single provider makes for easier dossier compilation
- ❑ Compliance – Governance and auditing easier – builds confidence
 - ❑ Continuous improvement embedded in the Alliance
- ❑ Regulatory – contribute jointly on draft regulations
- ❑ Shared science
 - ❑ Science Advisory Group
 - ❑ Access to 300+ bioanalytical scientists across both organisations
- ❑ Cost reduction
 - ❑ AZ FTE supporting clinical bioanalysis significantly reduced
 - ❑ Unit cost of bioanalysis considerably lower under the Alliance
 - ❑ Covance have a view of the revenue stream from AZ





Clinical Bioanalytical Alliance

- TRUST
- True collaborative partnership
- Mutual benefits realised
 - Process improvement
 - Efficiencies
 - Science
 - Behaviours
- CBioA model used as a template for future partnerships in AZ



To all those individuals from
Covance and AstraZeneca who
have contributed to the success of
the Clinical Bioanalysis Alliance –
You know who you are!