Biogen
(Boston, MA, USA.)

# *Data Automation Strategy for Data Science & Operations*

## *ENTERPRISE ARCHITECTURE CASE STUDY for ACHIEVE INTELLIGENCE*
*Version 1.0*
*January 2019*

*Note: certain people and product names have been redacted to preserve confidentiality.*

# Contents

# Introduction to Biogen

Biogen is a major Enterprise within the global pharmaceutical sector. The Analytics & Data Sciences Division consists of four departments, collectively responsible for delivering quality data and analyses to support the submission of drug and biologic applications to regulatory authorities. The **Data Science & Operations** department are responsible for the collection, statistical analysis and reporting of clinical data, supporting the other three areas, BioStatistics, Epidemiology and Biomarker Statistics.

# Purpose of engagement

At the time of engagement, Biometrics were looking to streamline their data value chain by automating as many of the manual tasks as possible, in order to decrease study timelines and either re-appoint much needed resource elsewhere in the organisation, or to take on more studies to develop more products. Biogen, therefore, required a quantifiable, fact-based and independent assessment of their existing processes, definition of their current challenges and a proposed target architecture focussing on data automation, with a high-level roadmap describing how to transition to that desired vision.

# Approach

Biogen leadership engaged Achieve Intelligence to provide Enterprise Architecture services: to define the current state of Biogen's Business, Data, Applications and Technology domains; to formally identify the problems; to uncover the overall vision; and to provide an effective roadmap for the transformational journey, away from the current state and towards an agreed vision state, specifically regarding Data Automation.

Using TOGAF® 9.2 methodology, Achieve Intelligence performed stakeholder identification, defined architecture principles, identified 18 business scenario challenges, facilitated a "Vision State" design thinking workshop, performed a gap analysis, drafted solution concept diagrams, and recommended an implementation roadmap with costs, timescales and potential return on investment.

Finally, this was collated in an Executive Summary report for review by the senior leadership team.

## Stakeholder Identification

The TOGAF® 9.2 approach to stakeholder identification is collaborative and democratic ensuring that every stakeholder has their say regardless of their leadership style and personality type. We adopted this approach at Biogen that resulted in identification of which stakeholders needed what level of communication, regarding project outcomes and input on decisions.

24.3.3 Stakeholder Approach: Power vs Interest
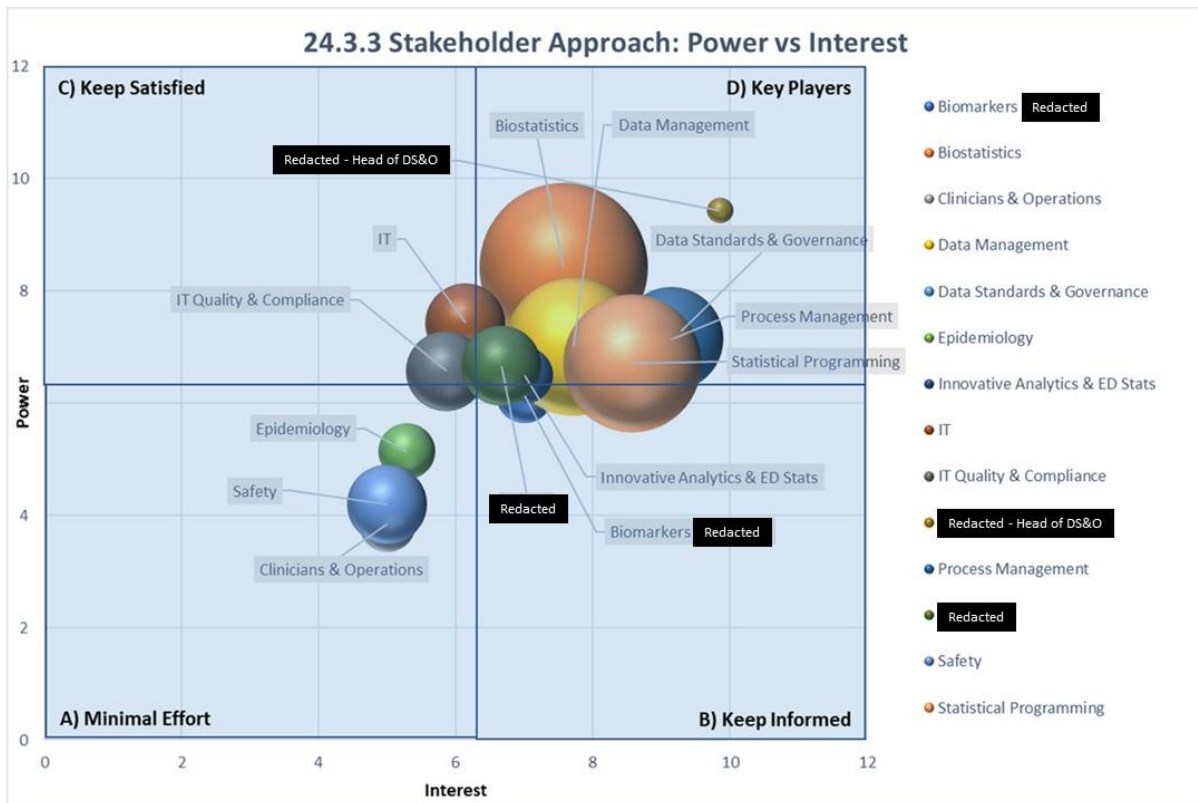
## Architecture Principles

Nine architecture principles were defined, debated and agreed by the operational team. These principles enabled effective decision-making when assessing options to progress from the current state to the future vision. Options in conflict with these agreed principles were discounted from outset.
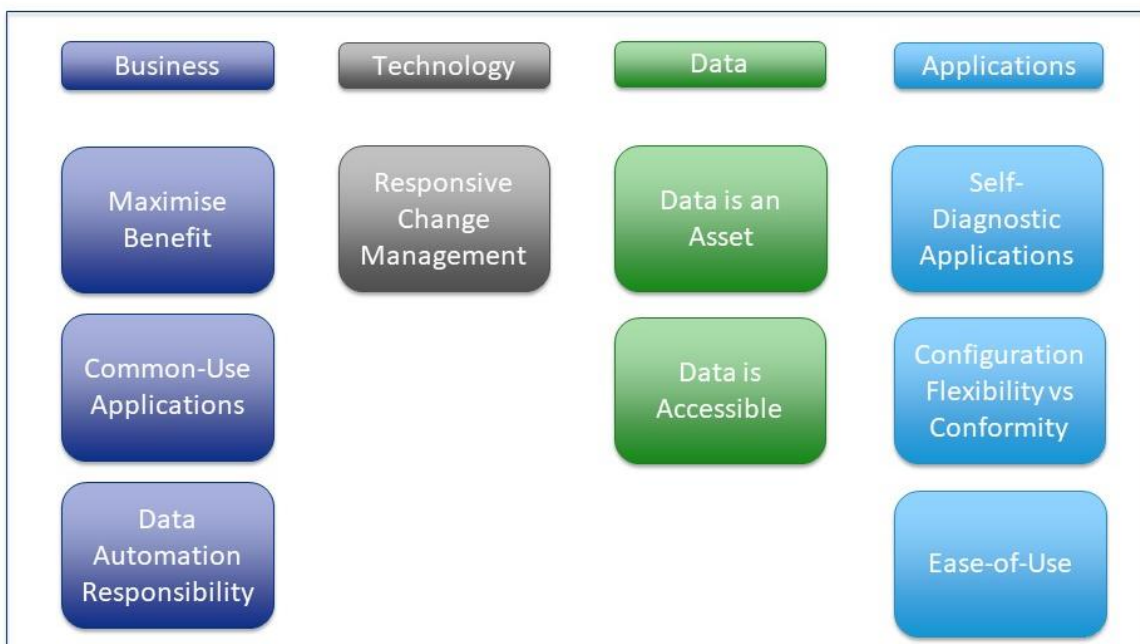
## Business Scenarios Definition

Each key player contributed to identifying 18 unique business scenarios within the data automation context. Some of these were more pressing problems than others, and several were identified by more than one stakeholder. These business scenarios fell into 4 general categories:

- Automated Data Artefacts
- Near Real-Time Delta Updates
- Automated Edit Checks
- Automation Tools Integration

These business scenarios were brought forward into a design thinking session to democratically investigate the problems and potential solutions.

## Vision State Design Thinking workshop

At Achieve Intelligence we merge the "left-brain" TOGAF® 9.2 methodology with the "right-brain" Design Thinking approach to ensure every stakeholder is heard and engaged. With Biogen we hosted a Design Thinking workshop to fully understand the business scenarios, frame the problems from a positive perspective using "How might we…?" statements, and ultimately design potential solutions from a well-grounded empathic understanding.
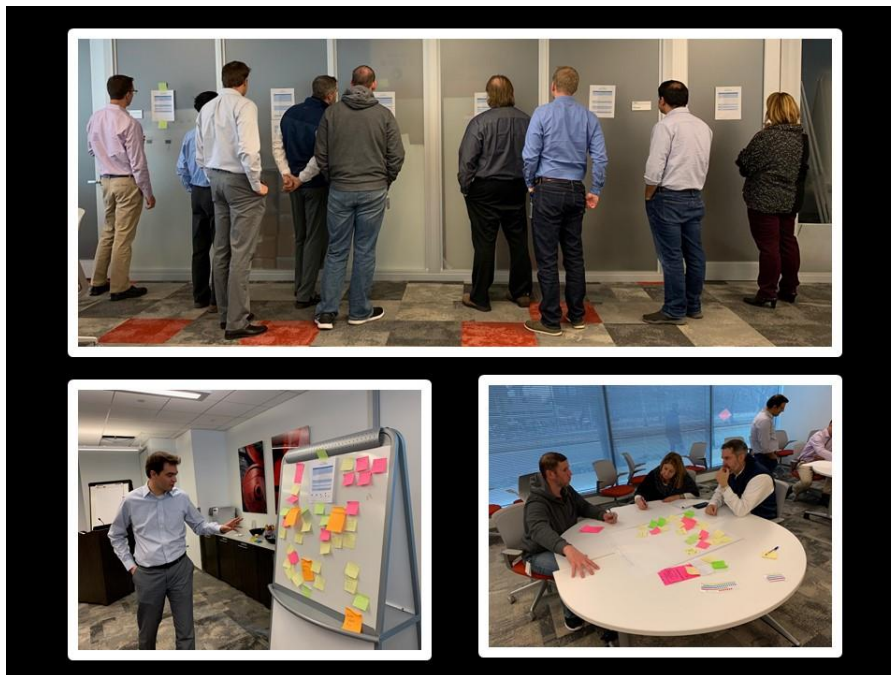


The output from this session was displayed around the offices for the next week, where other members of the organisation continued to contribute with new insights, suggestions, and further solutions inspired by this work.

This collaborative approach, to the problem/solution design flow, was then collated into distinct Architecture Building Blocks(ABBs), which exist in the current enterprise structure, and future state ABBs, which were required to enable the visionary solutions designed in the session.

## Gap analysis

A critical aspect to the transformational approach is the analytical work to determine gaps between the current state of the organisation and the desired future state. Following this methodological approach Achieve Intelligence were able to determine which ABBs could continue as-is in the future, which ones needed modification (such as upgrades to functionality or re-training of staff to utilise functionality correctly), and which ABBs needed to be replaced completely either through being superseded by a new processes, systems, or technology or by being combined with other building blocks which perform the same or similar function.

This small, yet vital, work package, easily highlights whether the move towards the desired vision state is a small evolution, or a large transformation. Executive Stakeholders find this information extremely useful mid-way through the project to be able to gauge conceptual effort and timescales required for the whole transformation programme.

## Solution Concept Diagram

The next step produced a set of Solution Concept Diagrams (SCDs) outlining the vision state for the business, applications, data and technology domains, based on information determined from the design thinking and gap analysis work. In this instance no changes were required for the underlying technology, so we re-distributed effort to concentrate on the data flow – which was the on critical change path.

This Data Architecture SCD defines the proposed future state of the clinical data flow. Each block is an ABB, each ABB has a list of potential candidate software/methodology which could perform that function. (Several ABBs have been redacted to preserve confidentiality).
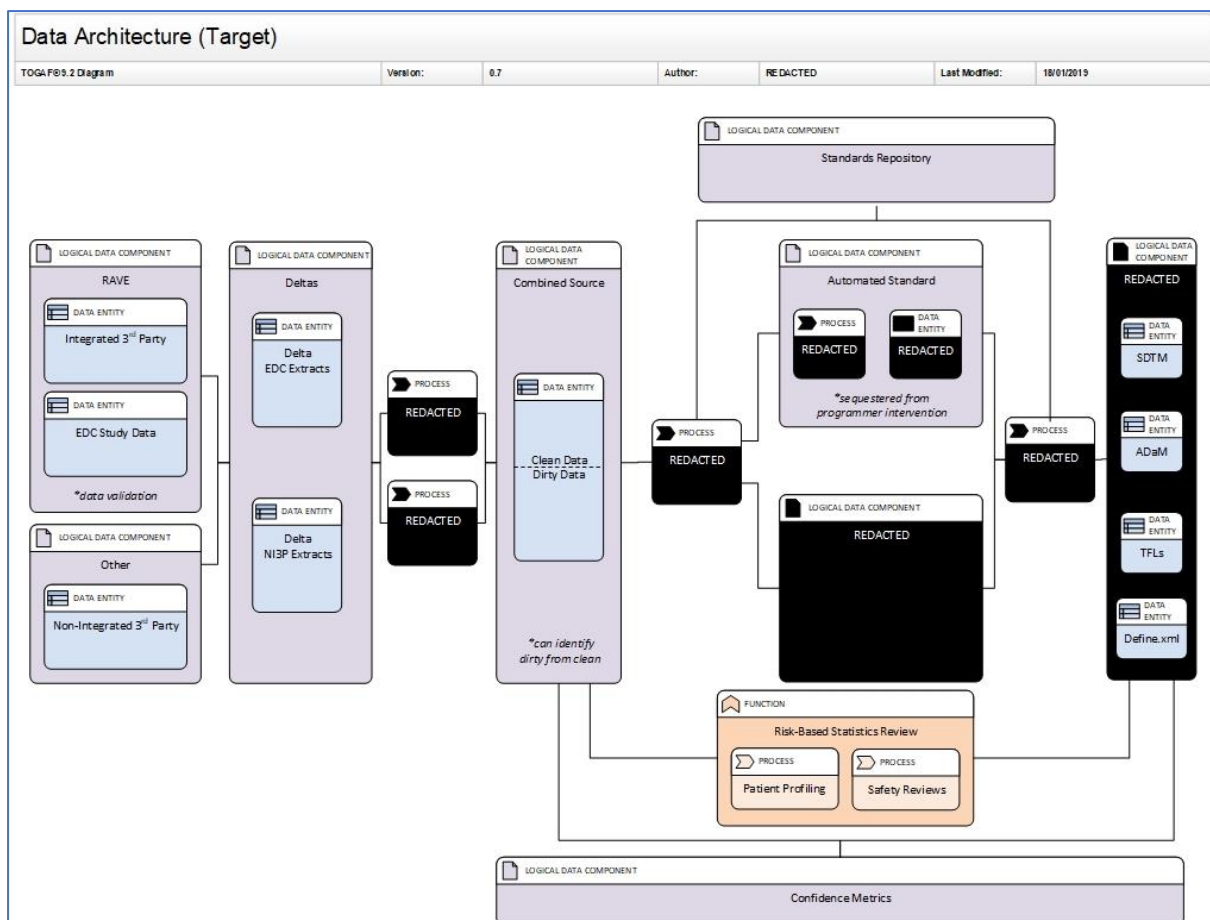
## Implementation Roadmap

Having captured and communicated the current state, and defined and agreed the future state, the next important question is how to get from current to future in the most cost-effective and least-disruptive way.

We defined an implementation roadmap, to guide Biogen through the change programme, ensuring dependencies are considered and addressed, and defining which Architecture Building Blocks need modification / replacing within which project.

Example timelines and resource costs were also calculated and given to the customer to adjust and modify, to align with their desired timescales and budgets.

## Executive Summary

The final step for this organisation was to present an Executive Summary outlining the outcomes and findings from our Enterprise Architecture work.

This summary discussed the current burning issues, the desired Vision State and highlighted the candidate software and methodology options which could be selected for further Request for Proposal (RFP) projects driven by the IT department.

# Our Philosophy

Achieve Intelligence's philosophy:

*Enterprise Architecture is a journey, not a destination.*

All the artefacts generated to support this project were left with the customer, to continue to use whilst developing the breadth and depth of their Business, Applications, Data & Technology Architecture.

# Customer Endorsement

*"Automating the process by which we transform our clinical trial data structures from data capture, CDASH, to downstream regulatory standard targets such as SDTM and ADaM, has been a hot topic for years in the Pharmaceutical Industry.  The value proposition is quite clear and significant.  Automation should deliver improvements in speed, quality, and cost.  Many made the attempt, most made progress to some degree, but no one has delivered a scalable solution that truly becomes disruptive to how we work in this space.  Standards and standards adherence is the standby.  At Biogen we strive to innovate and bring automation to realization.*
*Achieve Intelligence were brought in to help the team effectively design and plan for a data reporting automation program.  They leveraged design thinking, brought in industry examples, and ended with a viable automation roadmap as their final deliverable."*

**Jason Raines**
Head, Biometrics Data Sciences & Operations

*"I really like the way the Achieve Intelligence consultants challenged our pre-conceived ideas. They weren't afraid to speak up and suggest alternative approaches from their external experiences, whilst understanding the unique culture of Biogen."*

**Daniel Boisvert**
Senior Principle, Biometrics Technology & Innovation