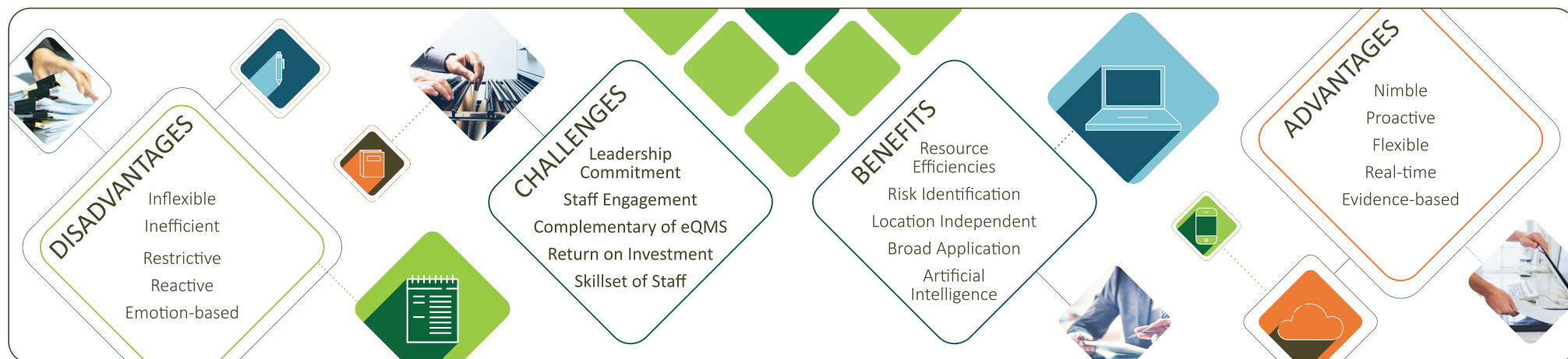


EVOLUTION OF A DINOSAUR

IMPLEMENTATION OF MASTERCONTROL™ IN A GCP CLINICAL RESEARCH ORGANIZATION



Case Study: MasterControl™ is a modular Electronic Quality Management System (eQMS) with a number of modules that interface with one another. Any number of modules may be implemented. The system is a 'Configurable Off The Shelf' (COTS) system, meaning that while basic elements of the code cannot be altered, you can configure the system to line up with your own processes and company terminology to the greater extent. This case study examines the implementation of MasterControl™ within a Clinical CRO which conducts full- and part-service Clinical Trials on behalf of Sponsor companies, moving the QMS from a paper to an electronic system. The modules were implemented using a phased approach, starting with Controlled Documents and Training.

Process Challenges:

- Initialization of the System with existing paper records
- Aligning the eQMS with your processes to avoid non-system workarounds and automate/standardize as much as possible

Strategy Challenges:

- Ensuring the records you import are not mid-revision
- Ensuring stakeholders understand the base elements of the transition from paper to electronic and what they should expect

Roll-Out Challenges:

- Training: Does everyone know how to log on? Have your processes been updated to reflect the use of a eQMS?
- Is everyone prepared for the initial notification and set up to access the software using the right browser with the right settings?

Recommended Approach:

- Start with the current version of your records, historic files with scanned paper records can be maintained outside the system
- Embrace the functionality of the eQMS and map your processes around those functionalities

After GoLive Challenges:

- Validation documents need to be audit ready
- Resolution of technical issues and onboarding and training of new hires

Gillian Birnie

Senior Director, Corporate Compliance, Veristat
gillian.birnie@veristat.com