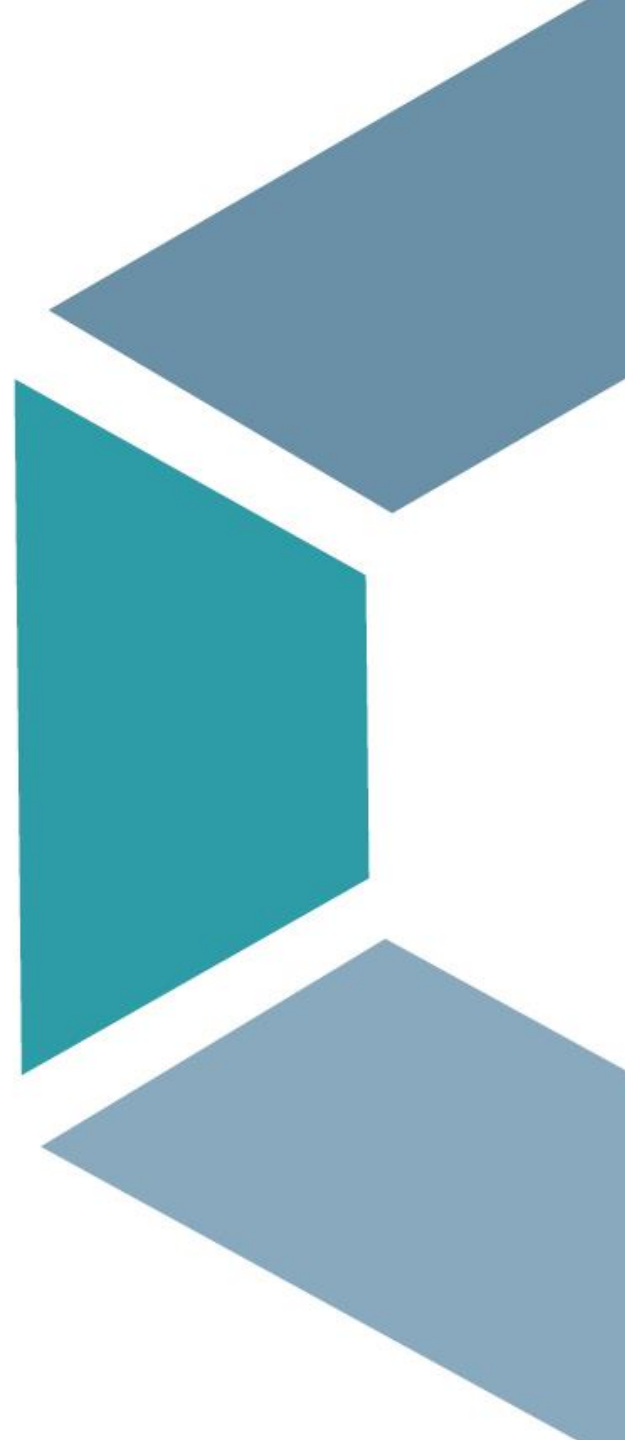




# Healthcare Digitalization

Considerations and challenges  
when implementing GxP systems

12<sup>th</sup> November 2019



# AgosIT Founder & Chief Operating Officer

## Liam Rogers

ITIL Expert, Chartered IT Professional, Agile Practitioner, ICH GCP Data protection In Clinical Research certified, ICH GCP Document Management and Archiving certified.

- Joined the IT industry in 2006 working as a Product Engineer.
- Joined the Pharmaceutical industry in 2008 working as an IT Engineer initially helping to develop a technical framework for a healthcare solutions company.
- Established a Global CRO's IT environment, successfully helping to support worldwide client and regulatory compliance.
- Worked as a Global Group Head of IT for a fast track FTSE 100 company, overseeing three business units in Clinical Research, Clinical Trial Supply and Early Access Programmes, developing solutions with GCP, GMP and GDP requirements.



# Considerations

- Complete a gap analysis - identify GxP system need
- MoSCoW is an effective prioritization technique
- Plan a phased delivery
- Consider internal skills, look for external partners
- Allow time for vendor selection
- Demand stakeholder involvement
- Prepare internal resource involvement
- Appoint a Project Manager
- Appoint a System Manager or System Owner
- Risk Based Validation is required
- IT department or IT provider involvement
- Configuration vs Customization

# Challenges

- Investment/ buy-in
- Cultural transition
- Acceptance of change
- Technical reassurance
- Incorrect configuration / input
- Time
- Migration
- Training
- Resource
- System identification

# GxP Requirements

- 21 CFR Part 11 / EU Annex 11 compliance
  - Backup and restore
  - Data Security
  - Data Integrity – follow ALCOA
  - Validation
- ALCOA
  - Attributable: data and metadata must be associated to an individual e.g. named logons
  - Legible: data must be presented in human readable format and made available to the regulator upon request
  - Contemporaneous: Data must be produced and recorded immediately, and a time stamp appended
  - Original: Data must be as generated
  - Accurate: Data must be permanently linked to the metadata

# The Partner Solution...

## Specialized IT Services

AgosIT offers bespoke, globally accessible, outsourced IT solutions to Pharmaceutical, Biotech, CRO and Healthcare organizations, to assist with choosing, deploying, running and expanding technology needs, while keeping regulation, data integrity and compliance requirements at the centre of the solution design.

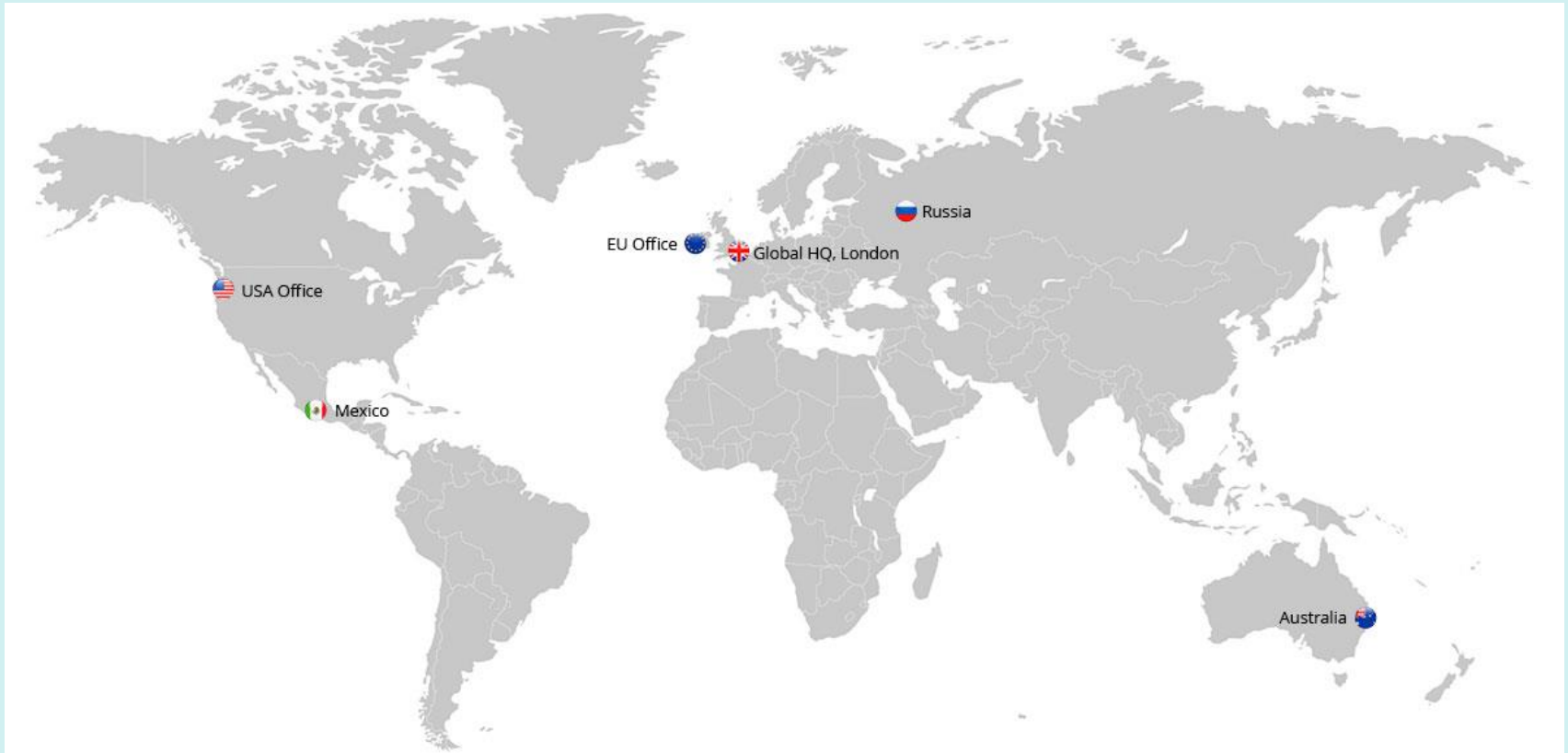
We ensure:

- Successful inspection and audit outcomes.
- Technology compliance to industry specific regulations.
- Greater cloud integration between GxP and Non-GxP systems.
- Robust IT security technologies and policies.
- Fit for purpose industry specific software solutions.
- Industry experienced outsourced IT support.



[www.agosit.com](http://www.agosit.com)

# AgosIT Locations

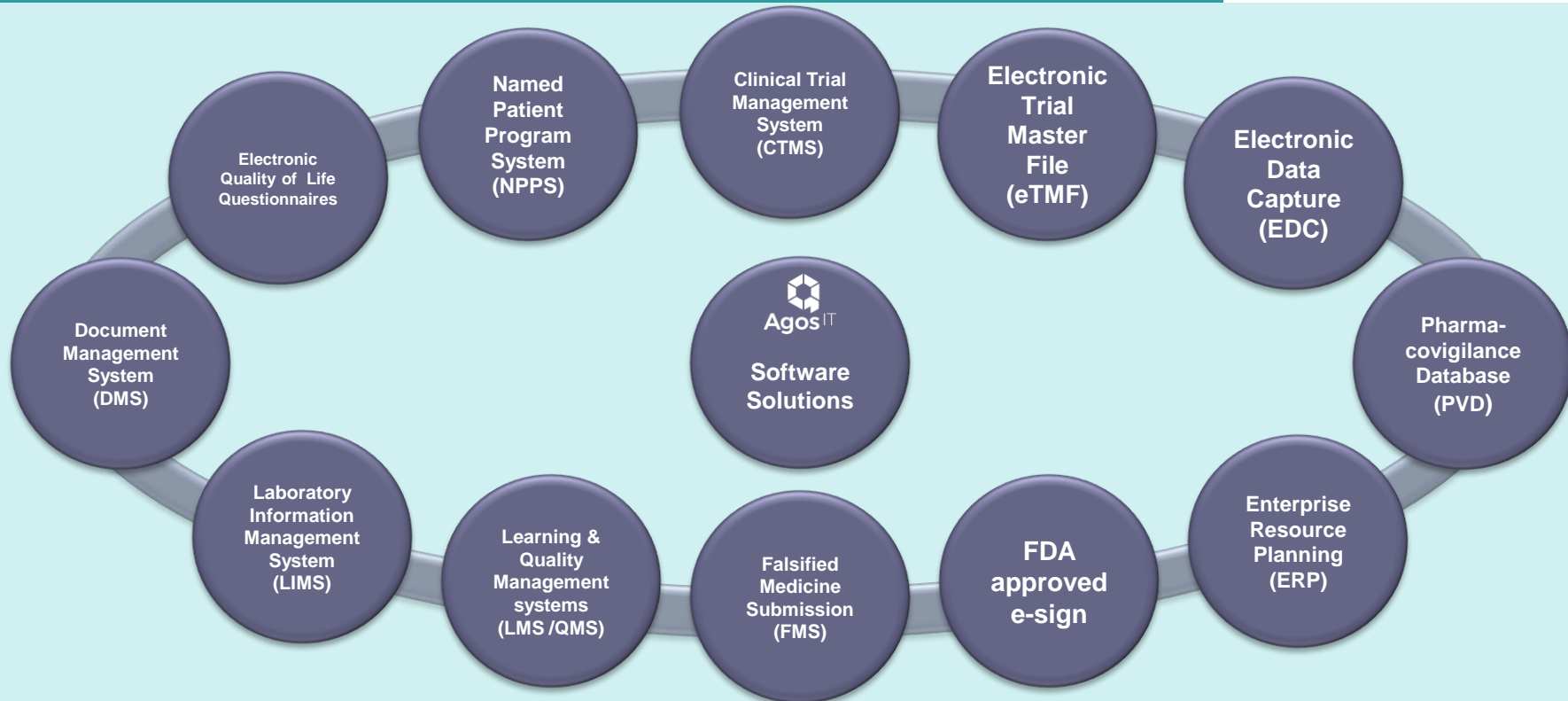


# AgosIT Services





# AgosIT GxP Solutions



[softwaresolutions@agosit.com](mailto:softwaresolutions@agosit.com)

[www.agosit.com](http://www.agosit.com)

## Questions & Contact Details



[www.agosit.com](http://www.agosit.com)

[info@agosit.com](mailto:info@agosit.com)

[www.linkedin.com/company/agosit](http://www.linkedin.com/company/agosit)

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