The Regulatory Blind Spot: *Unveiling Hidden IT Risks in Healthcare*

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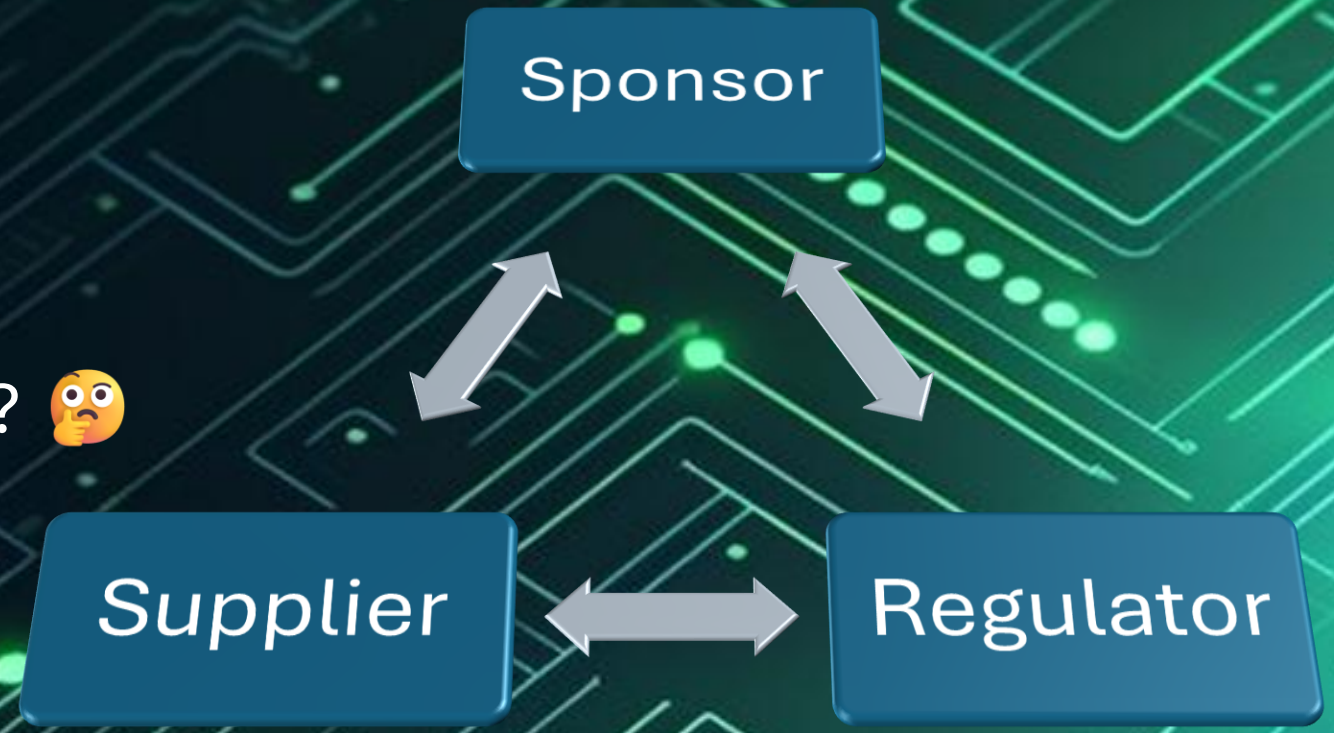
Setting the Scene

- **The Eternal Triangle:**
- Sponsor needs IT solutions
- IT supplier provides systems
- Regulator oversees sponsor
- But who oversees the IT supplier? 🤔



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Why Should We Care?

Because Things Can Go Wrong

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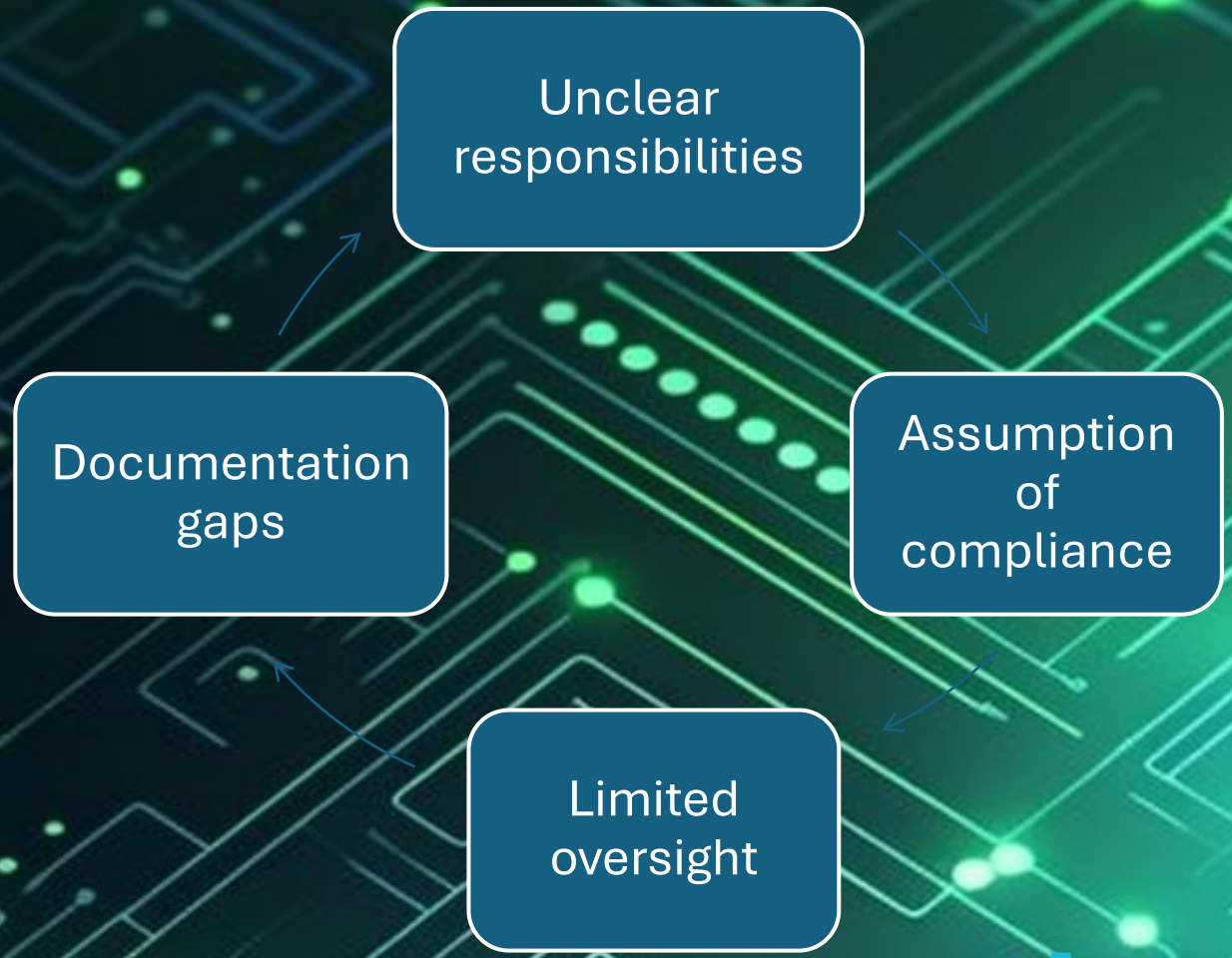
The Blind Spots Begin...



"They must know what they're doing" syndrome

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The Tale of Three Regulators

Or: How I Learned to Love the FOI Process

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FOI/FOIA Requests for IT Vendor Inspections:

GB MHRA (UK)

- Responded promptly
- Provided detailed inspection reports
- Redacted commercially sensitive info
  Clear findings and observations
- *"Here's everything we can share!"*
- However.... Only 2 IT inspections in the last 5 years

FOI/FOIA Requests for IT Vendor Inspections:

US FDA (USA)

- Searched their databases
- Couldn't locate relevant data
- Response: "No records found"
- *"Have you tried turning it off and on again?"*
- No inspections of direct IT suppliers in the database

FOI/FOIA Requests for IT Vendor Inspections:

EU EMA (EU)

- [Cricket sounds]
- [...still waiting...]
- [...checking email...]
- *"Your call is important to us..."*
- *Who knows???*

Key Takeaways

- Don’t expect FOI to give you what you require
- It takes patience to get there
- MHRA Process is by far the easiest
- FDA require specific details to provide information – without this nothing is provided
- EMA seem to have no active FOI service at the moment (multiple avenues attempted)
- *Transparency is like Wi-Fi - sometimes it's strong, sometimes it's weak, and sometimes it doesn't connect at all!"*

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Real World Examples

Based on MHRA inspection findings

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The Case of the Missing Audit Trail

Case Study: Endpoint Clinical IRT System Inspection (2019)

Background:

- Vendor provided Interactive Response Technology (IRT) for clinical trials
- System used for more than just IMP management
- Also handling clinical data collection & calculations

Key Findings:

1. **Audit Trail Accessibility Issues:**
    1. No real-time audit trail available to investigators
    2. Audit trail only available via back-end facility
    3. Investigators couldn't verify changes to their own data
2. **Quality Issues:**
    1. Complex format requiring expert guidance to interpret
    2. Decoding issues and filtering incompatibility
    3. Reason for changes not captured (key GCP requirement)
3. **Documentation Gaps:**
    1. No requirement to provide audit trails to client/investigator at trial end
    2. System access logs not included in standard deliverables
    3. Incomplete audit trail history in reports

The Case of the Missing Audit Trail

Root causes:

- Misunderstanding of regulatory requirements
- System design not aligned with GCP principles
- Inadequate consideration of investigator control requirements
- Lack of clear procedures for audit trail management

Key Lessons:

Systems handling clinical data must meet **ALL** GCP requirements:

1. Not just technical specifications
2. Consider regulatory compliance from design phase
3. Include investigator control mechanisms
4. Maintain complete data history

The Case of the Missing Audit Trail

Best Practices:

- Clear specifications for audit trail functionality
- Validation of audit trail accessibility
- Regular review of audit trail quality
- Documented procedures for audit trail management
- Training on regulatory requirements

"If it isn't in the audit trail, it didn't happen... and if you can't read the audit trail, nothing happened!"

Protocol Version Confusion

Premature Implementation

- Protocol amendment submitted for approval
- System updated with new version on June 26
- BUT… Ethics approval not received until July 1
- System allowing previously excluded patients
- *Fortunately, no patients enrolled during gap*

Protocol Version Confusion

The Mysterious Missing Protocol

- System built using draft protocol version
- Multiple amendments floating around
- Approved protocol never received by IT vendor
- Staff not trained on approved version
- Only "summary of changes" provided

Protocol Version Confusion

The Washout Period That Wasn't

- Protocol required 7-28 day washout period
- System specifications stated "No washout period necessary"
- Disconnect between protocol and system requirements
- No controls to enforce safety requirement
- *System couldn't ensure protocol compliance*

Protocol Version Confusion

Root Causes:

1. **Process Gaps:**
    1. No formal protocol version control
    2. Lack of regulatory approval verification
    3. Poor communication channels
    4. Inadequate documentation management
2. **Oversight Issues:**
    1. No requirement to receive approved protocols
    2. No verification of regulatory status
    3. Limited sponsor-vendor communication
    4. Assumptions about approvals
3. **Contract Problems:**
    1. No clear protocol management requirements
    2. Undefined approval verification process
    3. Vague amendment implementation procedures

Protocol Version Confusion

📋 For Sponsors:

- Must provide approved protocols
- Clear communication of approval status
- Regular oversight of vendor activities
- Verification of system alignment

🖥️ For IT Vendors:

- Don't implement without approval evidence
- Maintain protocol version control
- Document all protocol reviews
- Request missing documentation

⚖️ For Both:

- Clear contractual requirements
- Defined approval process
- Version control procedures
- Regular compliance checks

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The Sponsor's Dilemma

Common Challenges:

- Limited technical expertise
- Resource constraints
- Complex vendor landscape
- Regulatory uncertainty
- Time pressure

"We're not IT experts, we're pharma people!"

The IT Vendor's Perspective

Their Challenges:

- Multiple client requirements
- Different regulatory frameworks
- Rapid technology changes
- Commercial pressures
- Limited regulatory knowledge

"We're not pharma experts, we're IT people!"

Risk Mitigation Strategies

Key Actions

Risk Mitigation:

- Clear requirements
- Detailed contracts
- Regular assessments
- Documentation review
- Compliance monitoring

Prevention is better than remediation

Contract Must-Haves:

- Regulatory compliance requirements
- Validation responsibilities
- Documentation requirements
- Access to systems/data
- Audit rights

Get it in writing!

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Key Actions

Oversight Program:

- Regular vendor audits
- Performance metrics
- Compliance monitoring
- Issue management
- Documentation review

Trust but verify (again)

Getting It Right (First Time):

- Early engagement
- Clear requirements
- Regular communication
- Proactive monitoring
- Documented evidence

It can be done!!

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Warning Signs

- Resistance to audits
- Limited documentation
- Unclear processes
- Poor communication
- "We've always done it this way"

If it looks like a duck and quacks like a duck...

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Challenges

Partial Access:

- Only the ‘GxP Wrapper’ can be audited
- The core system is said to be proprietary
- Core system isn’t considered applicable to audit
- Very thin documentation set provided for ‘GxP’ instance of application

Challenges

Compliance Shell:

- Validated UI layer
- Unvalidated backend processes
- Mixed GxP/ non-GxP functions
- Very thin documentation set provided for ‘GxP’ instance of application
- Development tools and processes not part of audit

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Real World Impact

- Incomplete system understanding
- Hidden data flows
- Unknown risks
- Potential compliance gaps
- No regulatory inspections of systems
- Sponsor (or representative) is fully culpable for vendors actions

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Best Practice

- Clear audit rights in contracts
- Full system access requirements
- Complete documentation access
- Technical architecture understanding
- No black boxes accepted

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Thank you for listening

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