ALMAC

Whitepaper

Clinical Trials Need Preventive Maintenance Just Like Cars Do *and Here Is Why*

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Of Inspections and Partners

Inspections can be a bit stressful for everyone involved, there are additional stress factors when you have functions and responsibilities outsourced, or you've had some bumps along the way. The wording you never want to see is "There was a failure to ensure Quality throughout the course of the trial"

Project Teams turn over, people change roles, and depending on the length of your clinical trial – Investigators become more elusive as the trial marches forward. At Almac Clinical Technologies, we've seen a lot; to the tune of 110+ inspections supported each year. We've been through our own inspections and learned a lot along the way. We've learned what is being asked of us as a Partner and what the inspectors are looking at across the spectrum of clients in our portfolio. From the small biotech to the largest of the pharmaceutical companies. One theme has remained prevalent over the past few years: Oversight.

Oversight tends to be a loaded word, and one that invokes a very strong response in its meaning. We've asked this question during client meetings and at industry events, and one thing is clear there is a definite variation.

Each of these examples come from personnel at different companies, with varying opinions, and results vary between these approaches. None of these are wrong, and they all comprise separate, yet important parts of maintaining a robust approach to oversight.

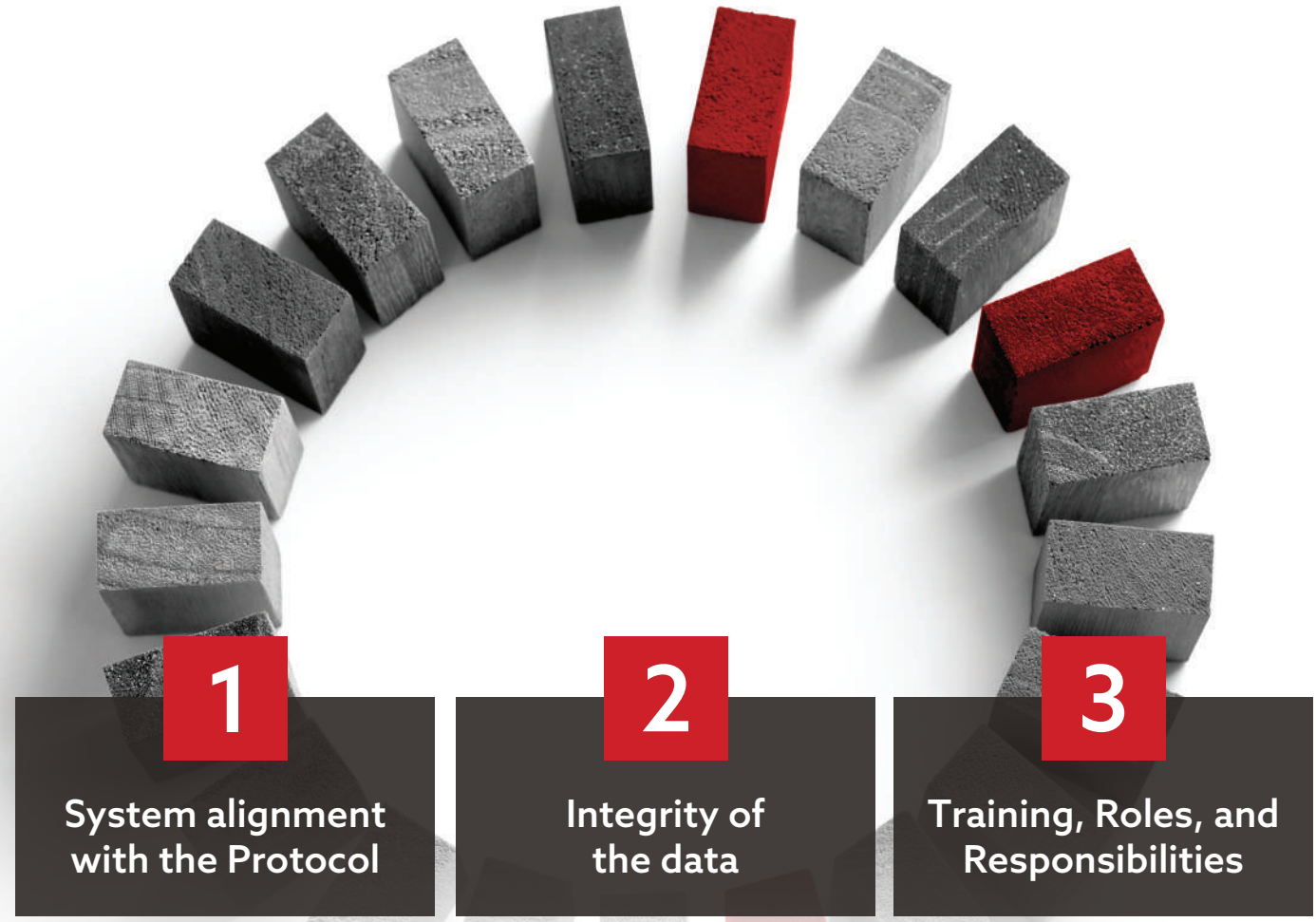
(A) The Data/Process monitoring ensures the information being collected is accurate, with the proper attributes, while being retrievable and traceable. **(B)** The contractual obligations are there to ensure data is accounted for and contemporaneously available, and **(C)** the data reviews and data managers ensure accuracy between systems.

Providing proper oversight has the potential to become an untenable standard that consumes resources and causes more non-compliance, however if you trust your partner, and trust the process, it becomes something that is easily manageable and can strengthen already existing internal processes.

Leverage Experience - Move Beyond Vendor and into *Partner*

One area we should start with is looking at the existing relationship. The personnel and companies providing e-clinical systems have the expertise in that area. It's important to listen to their input and identify areas where the two companies can complement each other, rather than attempting to force solutions and compromises.

We generally see these as the key areas inspectors focus on:



7-10 years ago, the questions were simple: "Is the system validated?" "What were the roles in the system?" however, as e-clinical systems have become more prevalent and accepted, they've become more complex. Inspectors are looking more into the functions of the system, integrations, and downstream usage. This becomes critical when the IRT is the initial point of entry. The data entered becomes source data and acts as a de facto eCRF. That data is investigator owned data (per ICH E6) and needs to remain in their custody. We've worked with our clients to help address findings and gaps they may have in their processes. Recently, we worked to identify data modifications trends that may represent a lack of site training, ways to reduce end of study reconciliation efforts, and where we can leverage our testing efforts to reduce UAT efforts and focus on key points.

When it comes to the idea of oversight- this is really where the definition should start: Understanding your partners processes. Keeping the communication channels open and having regular discussions about process, theories, and overall approaches. Having a conversation with a partner who runs 1000's of clinical trials can lead to some great insights and potential process improvements.

Who needs an oil change sticker? Just wait for the check engine light to pop on.

Regardless of the planning and preparation prior to the inspection there are often gaps. We see requests come together for requirement documentation, UAT scripts, Project Scope documentation, services offered, and client signed system acceptance forms. This is generally followed by a request to either provide the audit trail or provide a subset of the audit trail around data modifications. The client inspection team is often interested to see what types of data modifications were made or requested during the conduct of the trial, some of which may have been made years ago at the beginning of the trial.

We've heard from our clients that there is often a high level of effort to reconcile the data prior to the inspection and ensure the site files along with other systems are in alignment. Nothing like adding to an already stressful situation, rather than a more proactive/contemporaneous approach. When we think of oversight this is one of the key tenants: performing regular, scheduled, reviews of the data rather than making it solely a pre-inspection activity. Systems, reports, and data are all in place and can be utilized to help maintain inspection readiness and show how a trial sponsor is maintaining oversight and availability to the data.

Many hands make light work

There is so much work that goes into a clinical trial. When you begin to look at the amount of data sources and integrated systems that number gets exponentially larger. IXRS 3 provides a series of reports and dashboards that give at-a-glance information for Clinical, Quality, Site, and Supply personnel. This allows for each of these critical roles the ability for them to be empowered and informed when making key decisions. The site personnel can plan accordingly for upcoming visits to ensure adequate staffing and coverage, while the Clinical team can have a global view of the data. The Clinical team, or designee, can look at site participation, PI/Site initiated data changes, or potential site non-compliance issues.

In practicality- this is a tremendous opportunity to implement oversight. The ability to have visibility into the data, look for changes to key points, and ultimately use that information for informed decisions. Excessive data changes may be representative of an unclear system design, or a lack of site training. The ability to stay ahead of supply issues is paramount to the smooth running of a trial. It gives the ability to show a controlled approach to managing the data and the trial. There is an additional opportunity here to leverage your partner to gain additional insights into support calls or other means to help demonstrate an awareness of issues and risks within the system. Empowering the various levels of personnel on the trial allow for a robust perspective of potential issues and make up another piece of the oversight picture.

Build a strategy not a checklist

The regulations state that the trial Sponsor and personnel must maintain oversight for all aspects of the trial. We've seen this be incredibly successful when companies move away from the idea that they need to perform oversight activities prior to an inspection or as an exercise to demonstrate they're meeting the regulation and move into the idea of continuous improvement and partnership.

Success comes when the process is trusted, there is open communication, and activities are utilized across various parts of the trial. The ability to see data changes in an easily consumable format can prove to be an early indicator of potential issues or design flaws that can improve the overall approach to a trial.

Conclusion

Thinking about an inspection when you're notified by a Regulatory Authority is like waiting for the engine light to pop on to think about an oil change: it's dangerous, risky, and ultimately would cost you a lot of time, energy, and money. Not to brag, but there is no other company that has the depth and breadth of experience when it comes to IRT and inspections than we do, and we've drawn on insights across our client portfolio to think about best practices and find the best solution. We're here to help sponsors understand how to use these preventive maintenance tools to gain efficiencies, reduce errors, and decrease their time-to-market. An effective partnership allows us to learn from each other, use each other's knowledge and execute a transparent trial that is always inspection-ready. How about getting matching t-shirts, too?

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About the Author

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