MAXIMIZING YOUR DATA QUALITY: OUR RELENTLESS JOURNEY

Better Data Enable Better Decisions

It's simple: You need to get the most from your clinical trial. So it's no wonder that at Covance, we're constantly asking: *"How can we deliver higher quality data to you, faster?"*

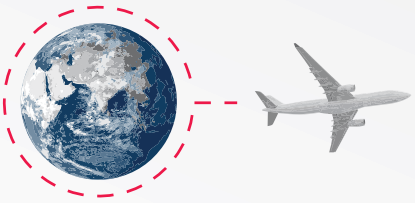
Your path to better data begins with your most precious asset: your samples. We are continually refining our processes to deliver better data from your samples, faster, while reducing risk. In this article, we'll explore our path to ISO 15189 accreditation, and what it means for you during a time of rapidly shifting regulatory expectations.

It started years ago. You told us you wanted better value for your studies. You needed increased quality and global scalability. We were already the industry leader. All of our central labs were operating under College of American Pathologists (CAP) accreditation. So we didn't have to change...but we listened, and decided to enhance our quality systems.

Quality Enhancements Driven by Global Standards

We knew the journey would be one that we would share together. You told us clearly that you wanted your labs to move beyond US-centric regulatory standards, encouraging us to embrace the new, more stringent global ISO standards.

So, in 2010, we began a systematic process of enhancing our Quality Management System (QMS). This allows continuous system improvements that translate into better communications and fewer errors. You would experience reduced risks—both to your samples, and from a regulatory oversight perspective. From the ground up, our enhanced QMS would be designed to align our processes with what is now known as the ISO 15189:2012 standard.



99.1%
OVERALL RECEIPT WITHIN STABILITY

To verify the effectiveness of our QMS and adherence to this global standard, we needed to engage an outside accrediting body. After a detailed review of our options, we chose CAP as our ISO 15189 accrediting body. They are thoroughly familiar with our labs and processes. They have demonstrated an in-depth understanding of the ISO 15189 requirements, and are respected worldwide for their commitment to ensuring quality laboratories.

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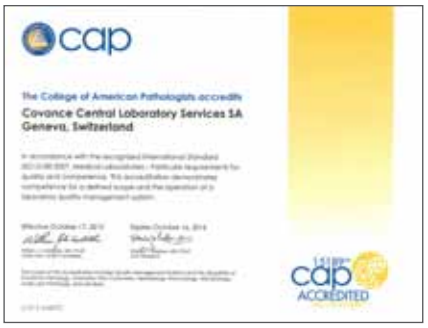
Your Needs Drive Our Accreditation Schedule



Please click here to view our certificate of accreditation.

We chose our central laboratory located in Geneva to be the first of our labs to go through the ISO 15189 accreditation process. Europe has led the way toward requiring this accreditation for medical labs. Clients with significant European patient populations were specifically asking for it. Adoption of the global standard in the Geneva laboratory would ensure consistency while still meeting country-specific requirements. In October 2013, our Geneva laboratory was assessed for ISO 15189 compliance, and received accreditation shortly afterward.

The CAP team performed the audit with full understanding and scrutiny that Covance is pursuing the more stringent ISO 15189:2012 compliance, although CAP had not yet updated their accreditation program from the 2007 standard requirements.

In June 2014, we expect our Singapore laboratory to be the first of our labs to be assessed to ISO 15189:2012 requirements. Indianapolis will follow later in the year. We will continue this process until all of our labs are accredited.

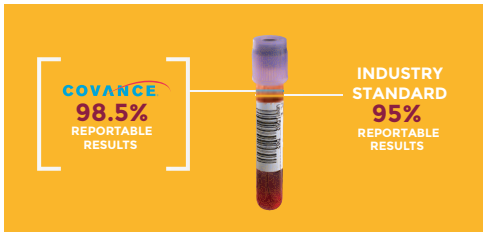
QMS Results in High Praise from CAP Audit Team

We were delighted to receive the following feedback from the CAP ISO 15189 assessment team during our Geneva accreditation audit:

> *"Overall, Covance Laboratory Geneva has a robust quality management system. The processes in place and the consistency in messaging between upper management and staff show evidence of the dedication and commitment to live the Covance mission of helping clients bring miracles of medicine to market sooner, and vision whose hallmarks are great people, high-quality data, and a proven track record of integrating and streamlining development processes."*

A Journey Shared

We want our commitment to be as clear to you as it was to the CAP assessment team: delivering the highest possible data quality, through globally optimized processes, is not a single event that can ever be completed. It is a journey we will continue to take side by side, enabling you to be more confident in bringing new treatments to market sooner.



What does this mean to you? Improved data quality and >98.5% reportable results saves you money by giving you more statistical power from fewer patients. Your enrollment and trial completion are accelerated with our dependable service delivery such as our extraordinary 97.9% of sites receiving first kits on time. It is more likely that your novel therapy can become the new standard of care.

While these data points are useful gauges of our progress over time, we still come back to the question: *"What more can we do?"* There will never be a final answer... the value is in keeping this question at the core of all we do.

Learn more about our drug development solutions at **www.covance.com**

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