



Background: Developing Highly Competent and Engaged Staff to Deliver Fit-for-Purpose Biopharmaceutical Solutions

Syneos Health, the only fully integrated biopharmaceutical solutions organization, brings together the best strategic brains in the business to help sponsors shorten the distance from lab to life. The company's 23,000 employees—a diverse set of clinical and commercial experts—power the creation of innovative solutions to help customers improve performance, reduce risk and expedite the delivery of therapies to patients worldwide.

To foster the development of a highly skilled clinical research workforce to deliver on customer needs, Syneos Health (previously known as INC Research/inVentiv Health) selected IAOCR, the accrediting organization for the international clinical research industry, as its independent workforce quality assurance partner in 2013. Committed to developing best practices and raising standards throughout the clinical research sector, Syneos Health has worked with IAOCR for more than five years to embed the organization's accreditation processes and programs into its work, further strengthening the company's clinical operations excellence while fueling customer success.

Take Away

The pioneering work conducted with IAOCR over the last five years, embedding workforce quality assurance processes into its core business, has enabled Syneos Health to deliver benefits for its customers and staff alike:

Benefits to Syneos Health Customers

- Improved quality and error reduction as indicated through customer feedback following positive audits
- Thorough training, accelerated development of a ready-when-you-need-them workforce
- Independent assurance of globally consistent, workforce-quality processes
- Clinical staff (clinical research associates, central monitoring associates and clinical data associates) who consistently deliver excellence; the processes and programs from IAOCR validate workforce competency and expertise against an international third-party standard, providing confidence that teams have the skills needed to bring new therapies to market

Benefits to the Syneos Health Workforce

- Career development and cross-departmental collaboration
- Robust professional development processes, including internationally recognizable Qualified Status Certification
- Clinical career progression based on objective assessment of competence
- Staff confidence in their own ability to deliver excellent customer solutions



Executive Summary:

Leading the Development of Best-in-Class Accreditation Processes

Syneos Health is committed to creating best-in-class processes that can impact the industry as a whole—developing leading site relations, driving industry conversations on new technologies and developing a more efficient workforce.

To gain true insights into how well it was servicing its customers and supporting its employees, Syneos Health began working with IAOCR to evaluate its processes and performance systems, leading to the deployment of a number of initiatives over the past five years.

By obtaining independent, internationally recognizable accreditation from IAOCR, Syneos Health has formally certified its level of performance, reassuring its customer base of quality delivery. For Syneos Health, this has contributed to strong business results, low staff turnover (even after the INC Research/ inVentiv Health merger) and positive customer feedback.

IAOCR's work with Syneos Health falls into two categories. The first is a holistic process known as Workforce Quality Accreditation (WQA), which was carried out by IAOCR on the Clinical Operations Group. Syneos Health currently holds the Silver Accreditation, which demonstrates that the organization prioritizes employee engagement and communicates its organizational vision, values, goals and objectives, as well as an understanding from individuals about the importance and relevance of their contribution in the workplace.

“When we started working with Syneos Health more than five years ago, they were the first global CRO to embrace workforce quality best practices—at the time most other organizations were simply focused on meeting regulatory requirements. Syneos Health goes above and beyond the required minimum—driving up industry standards. They have always approached accreditation in a very non-competitive way, encouraging others to get involved so that the industry can reap the benefits as a whole.

Syneos Health hasn't faltered from their commitment to the standards, even during the merger of INC Research and inVentiv Health; they placed importance on staying strongly committed to the path they had chosen.”

Jacqueline Johnson North
Chief Executive Officer & Co-Founder, IAOCR

The second area of focus has involved taking a competence-based approach to staff development at an individual level. This comprised the independent competence verification of clinical research associates (CRAs), central monitoring associates (CMAs) and clinical data associates (CDAs).

Through executing these projects with IAOCR, Syneos Health has identified a variety of benefits for customers, staff and the business.

“IAOCR continues to create meaningful collaborations to shape the evolution of the industry to deliver meaningful results for patients. This includes delivering best-in-class programs to support the expansion of clinical trials into new and emerging regions, continually elevating the level of experience and work quality.”

Alistair Macdonald
Chief Executive Officer, Syneos Health



The Challenge:

Deliver Consistent, High-Quality Work in a Complex Industry

A key distinguishing factor for any clinical research organization is ensuring that its people are able to deliver to a consistently high standard, regardless of their years of experience or location. Syneos Health identified that robust workforce business processes focused on competence and engagement were key to delivering this goal. The company's challenge was to ensure that its processes were world-class and would facilitate:

1. High staff retention
2. Being an employer of choice in the CRO sector
3. Robust evaluation of new and existing staff
4. Accelerating talent development for faster deployment
5. Improved employee performance
6. Improved quality and reduction of errors
7. Development of robust standards for new employees
8. Professionalization of roles mapped to international standards, and
9. Globally consistent HR processes related to competence and employee engagement



The Solution:

Two-Track Path to Improved Quality Standards

The overall goal was to drive up quality standards globally, and the company recognized that IAOCR's independence as an accrediting organization would ensure a robust, meaningful and objective approach.

IAOCR operates in a holistic and flexible way, blending consultancy and accreditation services that are focused on workforce excellence. IAOCR's approach was to work with Syneos Health to embed robust business processes focused on competence and engagement. Some of the processes were "off-the-shelf" and some were customized for Syneos Health.

Accreditation was undertaken on workforce quality processes as a whole as well as for individuals working in specific job functions.

Workforce Excellence

A Business and Clinical Trials Imperative



Clinical Operations Workforce Quality Accreditation (WQA)

Workforce Quality Accreditation is a continuous business improvement methodology that was perfectly aligned with Syneos Health's clinical operations strategy. It evaluates an organization's processes related to competence and engagement. The aims of WQA are to recognize what an organization is doing well, identify where the gaps are and help the organization to make improvements where needed. Once an assessment period has been completed, the organization is awarded a WQA Certification Mark (Foundation, Bronze, Silver or Gold), depending on the systems and processes that the organization has in place.

In 2017, Syneos Health (then INC Research) became the first CRO to achieve the Silver Level Clinical Operations Workforce Quality Accreditation. At this level, IAOCR:

- Examines an organization's "red flag" system for identifying lack of competence in high risk areas
- Establishes whether efficient and systematic performance management systems are in place
- Determines if employee engagement is an organizational priority
- Assesses the degree to which individuals understand the importance of their contribution to the vision, values, goals and objectives
- Considers whether the organization invests in developing soft skills and professional skills appropriate to the role.

“**Workforce Quality Accreditation is one of the most rewarding programs I have ever worked on. It is not a check box exercise, it's part of a continual improvement process—we learned a lot about ourselves: what we do well, what we can improve upon and how to fill gaps. IAOCR will not waiver from their standards—gaining the Clinical Operations Workforce Quality Accreditation really means something!**”

Richard Wood

Senior Director, Global Operations, Syneos Health

For Syneos Health, WQA provided confidence in the company's competence and engagement processes organization-wide, as well as providing a clear marker for customers on the standards they could expect and demand.

“**[Participating in the process] just made sense...it was clear that it would improve effectiveness and efficiency so, with a saving or improvement of 1 percent or 0.5 percent in a number of areas, it easily pays for itself while providing assurance of workforce quality to our customers.**”

Alistair Macdonald

Chief Executive Officer, Syneos Health



Qualified Status Certification for the Syneos Health Workforce

IAOCR also provides a wide range of robust, competence-based Qualified Status Certifications for clinical research professionals, supporting career pathways from entry-level talent through to executive leadership. The organization's accreditations are part of an effective quality-assured system that is mapped to the International Standard Classification of Education Framework developed by UNESCO.

After beginning with the accreditation of clinical research associates (CRAs) in the entry-level talent pool, IAOCR applied its competence-based approach to clinical data associates (CDAs) and central monitoring associates (CMAs).

The accreditation process started by having employees in the three job roles participate in comprehensive training courses run by Syneos Health's trainers. Each of the courses, and the trainers delivering them, were accredited by IAOCR using an approach based on the assessment of the trainers' competence and the learning outcomes and content of each of the training courses. The next stage of the accreditation involved a rigorous review of post-training evidence collected by individuals in the three roles through everyday workplace-based activities. The purpose was to demonstrate competence, which was assessed against independently accredited learning outcomes.



The Results

For more than five years, Syneos Health has been dedicated to reviewing its internal processes to improve its external offerings. Embedding IAOCR's processes has enabled Syneos Health to raise the bar on what sponsors can expect from their CROs. Syneos Health's commitment to independently accrediting its workforce quality is part of the strategic approach to attracting and retaining great staff that deliver great clinical trials.

By working synergistically to put robust competence and engagement processes in place, IAOCR and Syneos Health have produced the following outcomes:

Satisfied Customers

Client Assurance/ Winning and Retaining Business: WQA helps to build the trust of new and existing customers by providing assurance that Syneos Health has the ability to execute projects. The accreditation provides sponsors with confidence that Syneos Health is committed to doing things well at an organizational and individual level.

Increase in Positive Feedback from Audits: There has been an increase in positive feedback from audits and fewer items that need attention. A recent auditor commented that the data management SOPs were well written and allowed much tighter control—a by-product of accreditation.

Global Consistency: IAOCR's independent approach provides assurance that workforce processes and individuals are working to create globally consistent standards.

Fitness-For-Purpose: Both Syneos Health and sponsors are confident that staff are fit-for-purpose, regardless of number of years' experience, because they have passed IAOCR's thorough and independent accreditation programs.

Improved Quality

Increased Compliance: SOPs have been tightened due to having well-defined learning outcomes and assessment criteria, which is part of the accreditation process. This has resulted in a more consistent approach to quality and an increase in compliance.

Increased Quality and Efficiencies for Customers: The predictability and risk control provided by the accreditation enables Syneos Health to reduce errors and subsequent rework, thus increasing efficiencies for customers.

Engaged Employees

Career Progress on an Objective Basis: The accreditation provides a solid foundation for career progression based on competence.

Staff Retention: Staff turnover at Syneos Health remains one of the lowest in the industry. Because of the structures in place through WQA, Syneos Health is able to transfer staff within the organization due to the appropriate learning and development opportunities.

Talent Acquisition: Having WQA has become a significant tool for attracting CRAs and other clinical candidates, as well as drawing executive leaders who wanted to be part of the development of the project, both internally and externally. In a market where CRAs are scarce, Syneos Health develops its own CRAs with a CRA Academy. Entry-level employees have a tangible career and future, being able to develop and enhance the company culture while working to the company's high standards.

Career Development: Syneos Health has seen an increase in clinical operations promotions across the company as it pursues a strategy of developing people from within and backfilling at the lower level.

Increased Profitability through Effective Deployment and Staff Retention

CRAs

Prior to IAOCR accreditation, entry-level CRAs who were recruited globally could not be fully assigned to customer projects within the first 6–12 months of their employment.

- After the CRAs underwent the accreditation process, Syneos Health's customers felt significantly more confident in the ability of the new CRAs due to the independence of IAOCR. This is reflected in the very high utilization of this group.

- None of the individuals that have passed the accreditation process have needed re-training.
- Long-term ramp-up strategies for large projects can be set up. For example, in projects with a three-year or longer ramp-up plan, the CRA Academy employees, who are deemed competent having gone through the IAOCR accreditation and have two or three years of relevant experience, are ready to be deployed. This has been especially vital in countries where there has been a shortage of talent.

CMAs

One of the key objectives for seeking accreditation of this group was to introduce consistent standards in what was a new role both for Syneos Health and the industry and to assure Syneos Health's customers as well as individuals being accredited.

- Ninety-eight percent of the CMAs achieving the accreditation were approved to work on customers' projects without further training. This compared with 85 percent of those who were not accredited.
- As a group, the CMAs felt more confident in their ability to deliver excellent customer service and that the accreditation improved recognition of their job role.
- Annual staff retention rates were 92 percent in the accreditation group compared to 72 percent of the non-accredited population.

“Through our work with IAOCR, we continue to improve as an organization and are better through our clinical teams than we were before.”

Richard Wood

Senior Director, Global Operations, Syneos Health

CDAs

Comprehensive training programs delivered by a number of local trainers were already in place for this group globally, and the accreditation was aimed at standardizing the staff development mechanism, ensuring that the training was focused on competence.

- In conversations with customers, Syneos Health has learned that there is general excitement in the industry about having accredited CDAs. Customers are also delighted to discover that accredited CDAs are a standard provision—there is no extra charge.
- Customers report that Syneos Health's CDAs are well-rounded and multiskilled.
- The CDAs themselves report feeling more confident, and the accreditation has been helpful in building good relationships between the data management group and the clinical group, particularly CRAs. The accredited CDAs have been able to explain their role clearly.
- The process of collecting real-life work examples for the portfolio of evidence as part of the accreditation has given people confidence that they are able to do the job.
- There is now an appetite for learning, which will help CDAs with their career paths to lead data manager and ultimately project data manager, the latter being a growing role within Syneos Health.
- Staff turnover in the group is low.

“IAOCR’s approach has revolutionized the way in which the clinical research industry develops and assesses staff. They led an industry-wide initiative to develop competencies and pioneer best practices. Before this, there were no globally accepted competency standards. Now we know if our staff are fit-for-purpose and if they have competency gaps that need to be filled.”

Tammi Masters

Associate Director, Training, Syneos Health

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What's Next?

Syneos Health is embarking on the quest for the Gold Level Clinical Operations Workforce Quality Accreditation in 2019. The assessment process will help ensure that the necessary workforce quality systems and processes are in place to certify a fit-for-purpose workforce that delivers consistently good service.

About Syneos Health

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. Our company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Created through the merger of two industry leading companies—INC Research and inVentiv Health—we bring together more than 23,000 clinical and commercial minds with the ability to support customers in more than 110 countries. Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. To learn more about how we are **shortening the distance from lab to life**® visit syneoshealth.com.