DOCS
Resourcing Excellence

A DOCS FSP Case Study

Improving the study start-up process by reducing contract negotiation times.

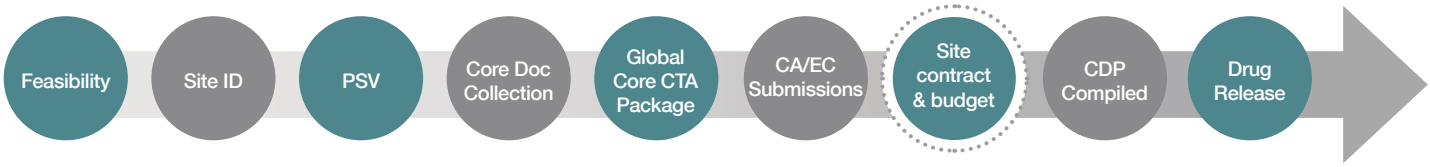
Emergence of new approaches to expedite investigator site contract negotiation.

Clinical teams are experiencing ever increasing pressure to streamline the study start-up process and reduce associated cycle times. The competing priorities of site identification and feasibility, negotiations of contracts and budgets, planning for patient recruitment, managing/tracking regulatory documents, and drug accountability render the start-up arena notoriously complex and time consuming.

For a great number of sponsors, the negotiation and sign-off of contracts and budgets with clinical trial sites is a major rate-limiting step for study start-up. DOCS were recently approached by a sponsor seeking to gain efficiencies at this critical stage for a large portfolio comprising of a number of challenging indications.

It is estimated that 70% of all clinical trials experience delays during start- up.

Study Start-up Process



Overview

- A leading biotech approached DOCS to manage all of their site contract and budget negotiations on a global basis for a key indication.
- DOCS proposed a pilot an FSP program, resourced with a global team of fully dedicated contract negotiators.
- The initial pilot program reduced negotiating of contract times by 45% as a result of improving the contract negotiation process.
- Due to the success of the pilot program, the sponsor has broadened the scope of the DOCS FSP contract to include their entire development portfolio.

Sponsor profile

- A rapidly growing, global biotechnology company.
- Specialising in complex indications.
- Adopting a mixed sourcing strategy comprising both in-house development and CRO-led studies.

Business challenge

- The challenge was to reduce study start-up times by improving the contract negotiation process, systems and resourcing algorithms with each study site.

How DOCS helped

- DOCS worked with the sponsor for 12 months and made a positive impact on the target indication group and the contracting process.
- The three key factors involved in improving site start-up times were:

  1. Implementation of a dedicated FSP model
  2. Targeted process reengineering
  3. The ability to clone site contracts

- The DOCS FSP model involved the assignment of fully-dedicated personnel in each country of operation. Each site was assigned a single point of contact within the FSP team who coordinated all aspects of the contracts and grant negotiation process. The reduced number of stakeholders and increased accountability for individual site start-up decreased the number of hand-offs, streamlined communication and increased satisfaction of site staff.
- The DOCS FSP team initiated a root and branch review of the site contracting process. Following extensive consultation, the sponsor adopted a number of best practices, including global contract negotiation SOPs, the deployment of ICON's innovative technology platform and the delegation of contract signature authority.
- Finally, the FSP partners embraced a policy of pro-actively 'cloning' language and budget items from previously agreed contracts. This enabled DOCS to speed up the contract negotiation process for those sites that the sponsor had worked with previously. As a result, certain key contracts could be finalised within 24–48 hours.

Outcomes

- The pilot program reduced site contracting cycle times by 45% compared with those achieved by the sponsor's previous FSP provider.
- The 45% reduction was achieved by improving the bottleneck caused by the existing contracts process.
- DOCS has been awarded the contract to run all the sponsor's clinical trials.
- Positive implication on study acceleration times yielding improved patient enrollment metrics.

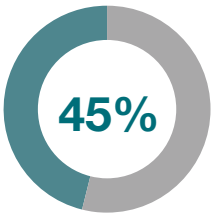
Improving Contract Negotiations Resulting In

Reduced contract negotiation cycle times

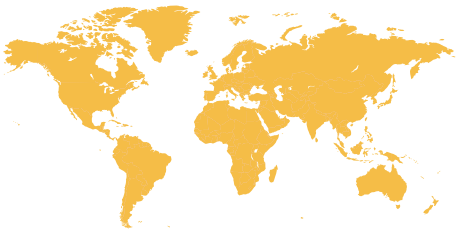
Increased Productivity

Improved Quality

Ability to finalise certain key contracts within 24–48 hours



45% reduction in site contract negotiation time



As part of ICON plc, DOCS is strategically located in 38 countries

DOCS is a leading provider of Strategic Resourcing solutions to the biopharmaceutical and medical device industries. Since our inception in 1997, DOCS has provided customers with tailored solutions across the entire resourcing spectrum. As part of ICON plc, DOCS is supported by approximately 11,000 employees operating in 38 countries.

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