Clinical development leaders had a strategic goal to develop protocols more rapidly. PI created a Strategic Playbook that redesigned the protocol development process with quality and speed, eliminating lost time and clarifying ownership. Then PI and the client partnered to implement the Strategic Playbook and achieve the client's goals – protocol cycle times reduced by half.

A midsized pharmaceutical company:

- Corporate leadership had a strategic goal to improve overall cycle-times throughout clinical development without sacrificing safety, quality or scientific rigor.
- Clinical development leadership targeted the protocol development process which had false starts, rework and delays.
- The client retained Pharma Initiatives partners to develop a Strategic Playbook to radically improve protocol development cycle times.

The recommendations in the Strategic Playbook **leading to a 50% reduction in the protocol development cycle time** included:

- Turning the process "on its head" by engaging stakeholders at the start of the development cycle that were used to being engaged at the end of the cycle to build in their feedback from the start.
- Developing some sections of the protocol "at risk" in parallel to reduce overall development cycle times.
- Eliminating lost time in the development cycle by tracking and enforcing rapid, efficient review timelines and measuring and posting results to encourage self-enforcement.
- Creating a single owner for each protocol who is responsible for driving the development cycle forward.

Embedding the changes recommended in the Strategic Playbook led to:

- **Process Optimization:** Developing standard operating procedures and guidance documents to document the new processes, including the timing associated with each step.
- **Organization Structure and Measures**: Documenting the role of the "Protocol Owner" and defining how it fit within existing positions; creating measures for the entire protocol development cycle using data from the work flow software.
- **Systems Implementation:** Defining requirements and modifying the existing document management systems to leverage existing but previously unused work flow capability to track timelines.
- **Training:** Developing and training on the new protocol development process.
- **Embedding Support:** Providing "Cycle Coaches" to provide extra support for staff during the first two protocols using the new approach.