ebook

Cognizant® Shared Investigator Platform (SIP)

Support for the “new normal” in the COVID-19 crisis

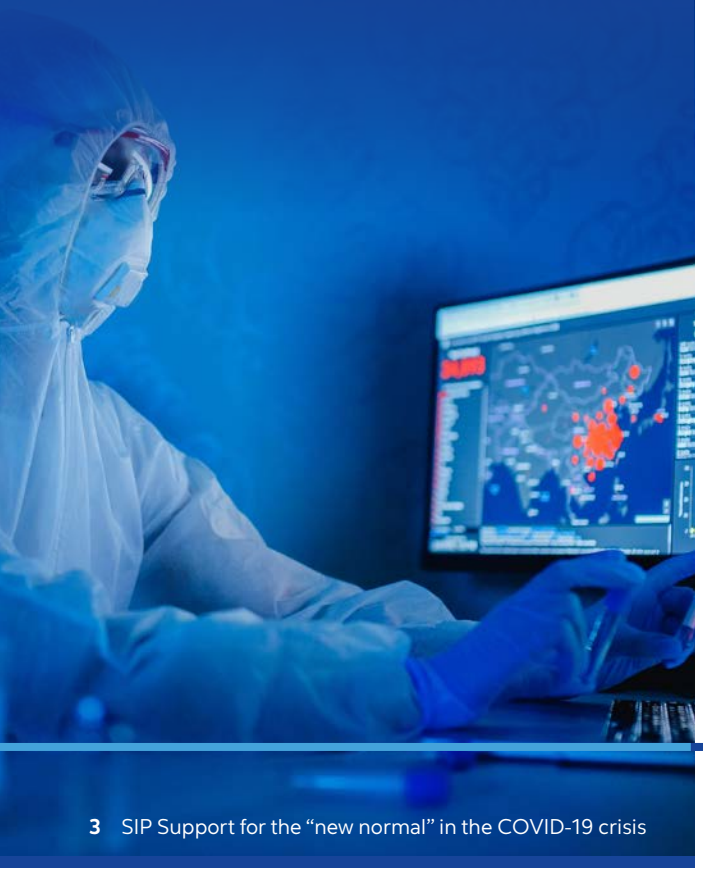
Cognizant®

"...Travel restrictions, quarantine measures or the COVID-19 illness itself may require changes to policies and procedures." The FDA identified the following specific areas of concern: "the informed consent process, study visits and procedures, data collection, study monitoring, adverse event reporting, and changes in investigator(s), site staff and/or monitor(s)." It recommends **"optimizing the use of central and remote monitoring programs to maintain oversight of clinical sites."**

– FDA guidance on conducting clinical trials of medical products during COVID-19 pandemic, issued in early March 2020

The Shared Investigator Platform (SIP)

supports the "new normal" in the COVID-19 crisis



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COVID-19 changes clinical trial execution

COVID-19 changed the world seemingly overnight. We went from "business as usual" to the "new normal" at warp speed. The impact of the pandemic will be felt by businesses across the globe for years to come. One of the industries experiencing the greatest impact is life sciences, particularly in the area of clinical trials.

In light of the new normal, the life sciences industry must pivot, transitioning from its traditional operating model to an accelerated, technology-enabled paradigm for drug development, clinical trials and regulatory approvals. To do that, the industry must leverage modern digital sciences and technologies to accelerate the development of new therapies and bring new, potentially life-saving treatments to market in record time.

When it comes to clinical trials, one thing has become abundantly clear in light of the COVID-19 pandemic—the traditional process of face-to-face visits and on-site monitoring needs to be reexamined. Widespread travel bans and health and safety guidelines, such as social distancing, has forced sponsors to find new ways to collaborate with trial sites.

With increasing pressure to accelerate drug development, enhance collaboration and reduce costs despite the challenges brought forth by the pandemic, many sponsors turned to the Cognizant Shared Investigator Platform (SIP), a robust tool that unites sponsors and clinical researchers.

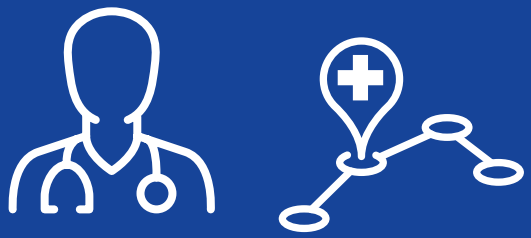
SIP transforms how sponsors and sites collaborate throughout the clinical trial life cycle, providing a solution for streamlining clinical trial set up and execution, and resulting in improved investigator experiences and increased collaboration across the clinical ecosystem.

The adoption of digital work practices like those provided by the SIP platform enables life sciences companies to adapt in the face of current challenges and not only sustain, but accelerate, clinical trials. This move to modern trial technologies is transforming the industry, turning a disruption into a change for the better.

Clinical operations adoption of remote monitoring

Traditional methods of conducting clinical trials have given way to new approaches in the COVID-19-altered world. Trial set up and execution have transitioned from in-person monitoring to remote, digital techniques that enable business to continue—and thrive—in today's environment.

Pre-COVID-19



Pharma clinical research associates (CRAs) / monitors travel three to four days per week visiting sites for prestudy, initiation, periodic monitoring and close-out visits.

Cost of site visits is approximately **$1,069,670 per trial annually** with an additional $42,700 per initiation visit.

During COVID-19

CRAs / monitors and some staff are unable to travel to sites during the epidemic. Clinical trials must transition to remotely monitored pre-study, initiation, periodic and close-out visits.

SIP is helping to enable the rapid transition to remote collaboration between sponsors and sites across the clinical trial life cycle.

E6-GCP does not require in-person visits, defining monitoring as "The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirement(s)."

SIP enables a rapid transition to remote collaboration between sponsors and sites across the clinical trial life cycle

PROTOCOL

Remote collaboration with data scientists, internal teams, key opinion leaders/ potential sites

SITE SELECTION

Remote management of trial site selection and activation tracking

MANAGE & CONDUCT

Remote training with recorded or live sessions

Secure verification and distribution of documents

Automated document flow between sponsor electronic Trial Master File (eTMF) and electronic Investigator Site File (eISF)

Centralize communications, drug shipment addresses, Institutional Review Boards (IRBs) and lab information

Remote gathering of investigator feedback

CLOSE-OUT

Remote, systematic management of study site/ study close-out

Verification of close-out documentation

Virtual close-out visits

Investigator feedback collection at close-out

RESULTS & REPORTS

Secure distribution of Clinical Study Report (CSR) and other reports and study results to sites

Currently supported remote clinical trial activities in SIP

75,000+
clinical researchers and

18,500 sites are ready to support COVID-19 research and all other studies.

Tasks and Delegation

Consolidates news, links and tasks across sponsors and studies.

Survey

Facilitates response to feasibility and study surveys across all sponsors.

User Profile

Includes sponsor searchable electronically signed "Digital CV."

Payment API

Integrates alerts and dashboards for full cycle of payment tracking updates.

Facility / Department Profile(s)

Describes the capabilities of each clinical location at which patients are treated.

Training

Reduces redundant training by securing credit through MRT and tracks study training completion in one location.

Organization Profile

Enables sites to proactively delegate SIP maintenance to the site support organizations with which they work, streamlining study start up.

Document Exchange Study Start Up

Collaborates, exchanges and electronically signs study documents and streamlines study start up with Document Packages.

Study Workspace

Gives sites access to all studies across all sponsors in a single location and eliminates data entry by enabling reuse of site details across studies.

Safety Exchange

Leverages a single inbox across all SIP locations, reducing the time needed to review and acknowledge Safety Letters.

Future SIP enhancements to effectively manage a trial in a post-COVID-19 world

SIP Enhanced Communications

Schedule remote meetings between site users and monitors with video and teleconferencing capabilities. Track meeting agenda and action items from the meeting.

Unified Digital Platform

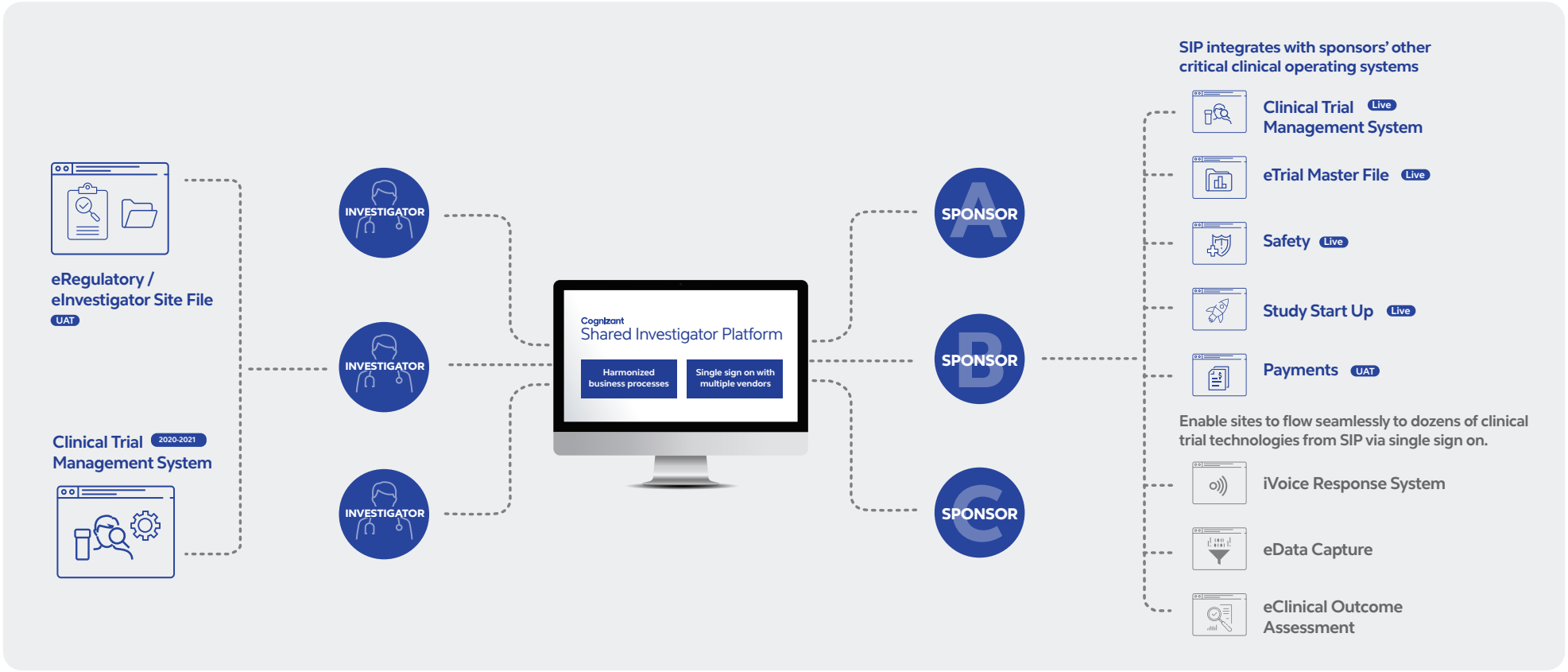
Enable integration with other Cognizant assets, like Digital Protocol, along with other partner vendors to provide a unified digital platform.

Expand SIP Partnerships

The SIP-connected clinical ecosystem is growing to include partnerships with leading eISF vendors, enabling the end-to-end flow of documents from eTMF to eISF via SIP.

The end state: a SIP-connected clinical ecosystem

Uniting all stakeholders across clinical trials



Future SIP Stakeholders Coming 2020-21

Clinical Research Orgs
Shared Investigator Platform
Institutional Review Board
Labs
Medical Devices
Regulatory Bodies

Future Partners Coming 2020-21

Electronic Health Records
RWE
Genomic

About Cognizant Life Sciences

Cognizant's Life Sciences business unit partners with biopharmaceutical and med-tech companies to develop strategies and apply solutions to healthcare challenges across the value chain. Our services and products, including the Shared Investigator Platform (SIP), are digitizing interactions between sponsors and investigators across every phase, helping the industry subtract time from clinical development and add it to patient lives. To learn more, visit **cognizant.com/life-sciences.**

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 194 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at **cognizant.com** or follow us @Cognizant.

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