Running Clinical Trials With Agility During COVID-19 Pandemic

Guillaume Couffe
Global Director, Sample Management Operations

EBF 13th Open Symposium
November 20th, 2020
Global R&D Labs Facilities and Relevant Specialty Testing Group Laboratories

- Covance Central Labs
- Extended Network Clinical Trials Facilities
- Covance Early Development Facilities
- LabCorp Specialty Testing Group or Premier Facilities

- Covance Central Labs
- Extended Network Clinical Trials Facilities
- Covance Early Development Facilities
- LabCorp Specialty Testing Group or Premier Facilities

- San Carlos, CA
- Endocrine Sciences, Calabasas, CA
- Los Angeles, CA
- National Genetics Institute (NGI), Los Angeles, CA
- Covance Central Labs
- Extended Network Clinical Trials Facilities
- Covance Early Development Facilities
- LabCorp Specialty Testing Group or Premier Facilities
Despite these challenges, Operations were maintained with limited to no impact to our deliveries
Crucial Role of Logistic Operations and Their Partners during the Pandemic

OBSERVATIONS DURING PANDEMIC
► Specialty couriers rely on commercial airlines; Massive cancellations led to poor performance
► Unprecedented cooperation between competitors to move samples between couriers and achieve delivery within the appropriate turnaround time (in stability)
► Role of logistics team in daily communications with couriers and project managers to coordinate delivery at the individual investigator level

CONSIDERATIONS FOR RECOVERY
► A professional, globally based logistics team will continue to identify which sites can safely be initiated with fewer concerns for courier-related delays
► New transportation lanes developed as a result of the pandemic
► Strong partnerships with couriers provides an unique early warning system for future issues (pandemic, weather, etc.)

COVID-19 Achievement:
96.9% all-cause stability during April 2020 (most challenging month)
EH&S/Facility Adjustments to Keep Laboratory Operations Running

- Review of the requirements from global and local authorities
- Review of the corporate requirements
- COVID19 crisis team internal discussion (Facilities, EH&S and operational stakeholders) to agree on the measures to be implemented

- Adaptation of the measures to meet the requirements from authorities and ensure employees safety
- Implementation of measures to ensure employees wellbeing in the facility

- WFH: for non-essential workers
- On site: Implementation of protective measures (Social Distancing, Handwashing, Personal Protective Equipment, Temp check)
- Frequent communications to all employees:
  - WFH: Training and video for re-entry for employees coming back on site after WFH period
  - On-site: via posters, kits with booklet,…
  - Work with supply chain to ensure PPE and hygiene products availability

- Dashboard to monitor the evolution of the situation and the need to adjust the measures taken
- Review of any new requirement from global and local authorities
- Weekly collection of employees feedback

Plan

Do

Act

Check
Supply Chain Adaptation to Meet Demand for Critical Items

**Business Continuity Plan**
- Identification and monitoring of critical supplies to be maintained
- Stock increase to avoid back order situations
- Procurement of PPE to support operations

**Virtual Operation & Communication Tools**
- Online office phone deviation to employees' mobile phone
- VPN system enabling access to all company systems
- Virtual Meeting tools (e.g. WebEx, MS Teams)
- IT network stability

**Proactive Supplier Communication**
- Communication with suppliers to assess impact on their operations and capacity to deliver
- Communication with external service provider to ensure the availability of their engineering teams

**Develop Alternative Solutions**
- Extensive new suppliers selection to diversify the source of supplies
- Temporary Covid-19 vendor set-up process
- Development of local solutions to reduce custom issues
- Look for opportunity to insource manufacturing of supplies

**Global Supply Back-Up Coverage**
- Use the global footprint of the organization to mutualize efforts, find additional alternatives and generate more applicable solutions
Lab Operations Continuity While Accelerating COVID-19 Assays Validation

Organizing Workload to Maintain Lab Operations
- Adapting the layout/workflow with reinforced protective measures
- Providing documentations for essential workers and custom clearance
- Leveraging laboratory methods/platforms to develop COVID-19 assay

Accelerating COVID Clinical Trial Support
- Leveraging our colleagues from LabCorp Diagnostics and their work accelerated PCR and serology testing - Assay available for clinical trial use within approximately 1 month
- Validating COVID-19 related tests to support clinical trials with a global footprint

COVID Diagnostic Support for the Community
- Leveraging our Clinical Trial laboratory to supplement the enterprise/diagnostic capacity or the COVID-19 EUA PCR for the general population at a critical time
Unprecedented Acceleration of Study Setup and Utilization of Patient-Centric Solutions
Covance Clinical Trials Testing Solutions Study Setup Case Studies

**SITUATION:**
- In March 2020, Covance began to receive an influx of interest in COVID-19 trials from both large pharma and biotech clients—all with expedited timelines

**ACTION:**
- In the Central Labs, the Streamlined Study Set Up (SSSU) team quickly liaised with key departmental roles to ensure study timelines could be accelerated
- In Bioanalytical labs, cross-organization collaboration for method development and validation acceleration

**RESULT:**
- Study award to kit shipment in 5 business days
- BioA method development and validation within 3 weeks
- Best practices and efficiencies have been documented to further streamline future COVID-19 and other studies
Remote Operating Model for Project Management and Administrative Functions

**Business Continuity Plan**
- Specific procedures for remote working setting
- Mandatory training for all employees on BCP with remote work
- Access to IT support

**Virtual Operation & Communication Tools**
- Online office phone deviation to employees’ mobile phone
- VPN system enabling access to all company systems
- Virtual Meeting tools (e.g., WebEx, MS Teams)
- eSignature system for internal workflow continuity
- IT network stability

**Proactive Internal & Customer Communication**
- Dedicated COVID-19 communication team
- Frequent and regular communication to internal teams and clients on COVID-19 impact on company operations and solutions to specific issues

**Team Cohesion Activities**
- Virtual Team Coffee
- Virtual Team event (e.g., video)
- Regular check up and virtual 1:1 meeting with manager

**Global Team Back-Up Coverage**
- Back-up coverage within global teams and function mitigating resource reduction due to absence and enabling delivery continuity
What Are the Key Lessons Learned from This Unprecedented Period?

- Passion around a very important mission – to reduce mortality of COVID-19 patients and to prevent our loved ones from getting SARS-CoV-2
- Cross-functional and cross-enterprise team allowed to challenge each other and remove barriers (Diagnostic and Drug Development)
- Need to constantly challenge Status Quo to develop new ways of working
- Need to be empowered to make decisions and move quickly
- Frequency of meetings & accountability are key to reactiveness

Our primary aim during this pandemic is and has been to **safeguard the health and well-being** of our employees and the community at large while **supporting the urgent needs of our Clinical Trials clients**.