WHITE PAPER

FluSync: Proactively optimizing clinical trial operations and aligning resources with integrated disease prevalence insights

A KEY QUESTION

How does Fortrea's approach differ from traditional CRO-sponsor relationships in optimizing clinical trial operations?

KEYWORDS

Influenza, Influenza-like Illness (ILI), Clinical Trial Operations, Heatmap Visualization, FluSync, Vaccine Development Antiviral Therapeutics, Diagnostic Research, Predictive Workforce Planning, Risk Monitoring System

Influenza is one of the most heavily surveilled viruses in the world. However, tracking the spread and incidence of influenza and influenza-like illness (ILI) presents significant challenges for public health agencies, drug development sponsors and clinical research organizations (CROs).[1]

Recognizing that existing methods for tracking disease incidence often fall short of clinical trial needs, Fortrea has developed a conceptual tool that automates the comparison of regional and site-level flu activity.

This white paper discusses the current inefficiencies faced in tracking influenza and explains how integrated analytics and automated site flagging can better inform decision-making and streamline clinical trial operations.

Examining the challenges of flu tracking

Seasonal influenza results in approximately one billion cases globally each year, including three to five million severe cases, creating a significant public health and economic burden.[2] In the U.S., influenza was attributed to an estimated 9.3-41 million illnesses and 6,300-52,000 deaths annually between 2010 and 2024.[3]

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As influenza strains evolve seasonally, clinical research plays a key role in improving the prevention and management of the latest influenza strains. Central Monitors and Clinical Research Associates (CRAs) supporting clinical trial sites must closely track ILI in their region to determine whether surveillance data from public sources align with the observed incidence rates at each site.

Ideally, the site-level ILI incidence should match the regional incidence. But tracking ILI and comparing rates is often a highly manual and fragmented process that typically involves:

- **Repetitive, time-consuming review of public data:** Searching and filtering multiple public data sources, such as the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), must be repeated for each review cycle
- **Siloed site-level data review and manual comparison:** Site-level data is extracted, calculated, reviewed and manually compared against public regional ILI
- **Ad hoc notification processes:** When large deviations occur, sites are individually tracked and the clinical operations teams are notified without a clear handoff process
- **Individual tracking of actions:** Sites are contacted to identify the source of the deviation, and follow-up actions are individually tracked

This fragmented and labor-intensive process limits clinical operation teams' ability to detect deviations in a standardized and efficient way. Corrective actions can be delayed or missed, and follow-ups can be difficult to track.

Integrating data and automating key steps

To address these inherent challenges with disparate data sources and siloed technologies, Fortrea's AIML Rapid Development Studio developed a conceptual tool called FluSync. At a high level, FluSync can support clinical trials by ingesting and analyzing public and internal data and then flagging sites with significant deviations from regional influenza trends. The team aimed to automate site-to-region comparisons with statistical rigor and enable faster, more reliable decision-making.

To test FluSync, Fortrea simulated multiple flu trials using synthetic sponsor data and leveraged real-world data from three external sources: WHO FluNet; CDC FluView; and the European Centre for Disease Prevention and Control (ECDC): European Respiratory Virus Surveillance Summary (ERVISS). The team evaluated each source for its accessibility, granularity, update frequency, methodological rigor and regional consistency. They also considered dataset limitations and their potential impact on the reliability of site-to-region comparisons in clinical trials.

After compiling the most recent regional ILI incidence rates, the team set a threshold for the relative flu rate, defined as a site's incidence relative to its locality (which can be configured in future iterations of FluSync). The product was configured to flag trial sites with incidence less than 0.5x or greater than 1.5x the regional incidence, and to test the ratio for statistical significance.

Visualizing influenza incidence tracking with heatmaps

To highlight deviations, FluSync generates a global heatmap of trial sites. The heatmap highlights areas with higher percentages of sites showing significant deviations in ILI incidence and includes automated alerts to flag emerging trends and sites with the most significant relative flu rate deviations.

At a more granular level, the region- or state-level heatmap view displays all trial sites, distinguishing those that exceed the predefined ILI relative threshold from those that do not. The interface also provides detailed information for each trial site, including the full site name and ILI incidence rate to support rapid assessment and targeted follow-up by the clinical operations team.

At a site level, FluSync provides more detailed information, such as its exact location on the map, ILI incidence rates, weekly trends and the site's relation to its regional incidence if it exceeds the predefined threshold.

Streamlining decision-making and actions with FluSync

To help streamline and automate data workflow for actionable decisions, FluSync users can initiate follow-up tasks and flag sites for review using "Contact" and "Create Issue" buttons. For example, CRAs could receive an action item to contact the site and track progress through a mobile CRA application.

Evolving FluSync to continuously improve clinical trial operations

The simulation demonstrated how FluSync could streamline workflows by connecting insights with operational platforms, such as a risk monitoring system and a mobile CRA app, enabling faster, more coordinated responses.

Informing resource allocation with FluSync: The Fortrea Functional Service Provider (FSP) perspective

To strengthen trial management and resourcing strategies, Fortrea FSP aims to proactively align clinical trial resourcing with disease prevalence insights from FluSync.

By integrating FluSync heatmapping data into strategic planning, Fortrea FSP can better anticipate trial demands and deploy clinical research professionals to the regions and cities where sites are most likely to be activated.

This forward-looking model reduces white space by addressing talent gaps that could delay trial execution. FluSync data can promote predictive workforce planning, accelerating both site start-up and patient enrollment. Coupled with dynamic and flexible resource allocation, Fortrea FSP envisions empowering sponsors and executing trials with greater speed, precision and scalability.

Looking ahead, Fortrea plans to pilot FluSync with a global drug development sponsor to assess its utility in a real-world setting, incorporate the sponsor's feedback and guide the development of new features. Fortrea also envisions expanding the scope of FluSync through initiatives such as:

- **Acquire additional data sources:** FluSync currently accesses U.S. databases and WHO data to track respiratory incidents. Fortrea is exploring additional country-specific datasets in Europe and Asia
- **Evaluate predictive analysis to support future influenza seasons:** While major regulatory and public health agencies face challenges in generating high-confidence predictions, Fortrea aims to leverage baseline geographic patterns against historical influenza strains to enhance predictive analysis
- **Expand FluSync technology to support other respiratory diseases:** Fortrea recognizes the potential to apply FluSync's approach to other respiratory diseases. While other respiratory diseases may lack global real-time public data on trends, Fortrea is assessing ways to use clinical data registries, lab-confirmed hospitalization data and other public health monitoring modalities

As influenza clinical research advances vaccine development, antiviral therapeutics and diagnostic research, Fortrea continues to innovate beyond the traditional CRO-sponsor relationship, applying new approaches to optimize clinical trial operations.

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