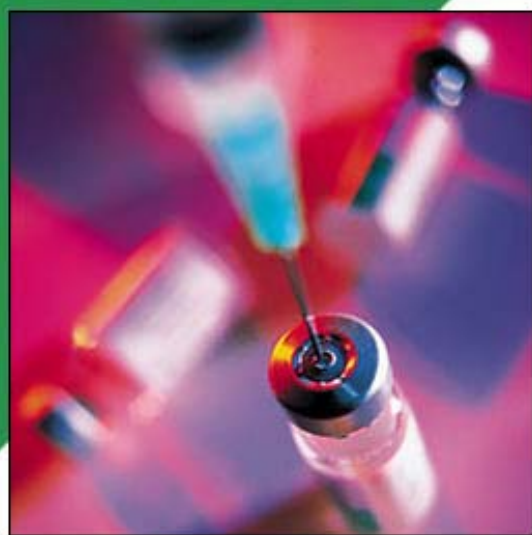


PDS Express™ for Vaccine Studies



The lineage of PDS Express™ began in vaccine studies. The founders of PDS developed the initial architecture of the system while they were working in the vaccine area. As a result, the system is exceptionally well adapted for the collection of data critical to the conduct of vaccine studies. Key design features ideal for vaccine studies include:

- a) Full time accessibility to data, including all safety data,
- b) Routine and esoteric laboratory data importation compliant with 21 CFR 11,
- c) Support for importing images and data from instrumentation,
- d) High performance on-line functionality
- e) Ability to employ alternate technologies when broadband connectivity is a challenge
- f) Transparent and uncomplicated pricing model

Any Time Access to Your Data

Although the efficacy endpoints of vaccine studies are generally a combination of both clinical outcomes and serologic data, the safety issues of these studies may predominate in the early phases of the study. Since inoculating hundreds of patients over a short time period is common, the ability to collect and examine data on subjects quickly is important to ensure subject safety.

In addition to serious allergic reactions, minor and moderate reactogenicity reactions may also be critical in the development of a prophylactic vaccine. This can be particularly important if the vaccine is in a highly competitive area. These data may reduce the commercial attractiveness of a vaccine to the point of making future development inappropriate.

Sponsors conducting vaccine studies use PDS Express™ to gather data from around the world to host it in a secure central location, to review safety data in real time, and distribute this data for review to third parties. PDS helps you to customize the data views for your audiences. For example, your safety group can assess the clinical response while the serologic data is blinded.

Importation of Esoteric Laboratory Data

While many EDC systems can import routine laboratory data in a manner compliant with 21 CFR 11, PDS Express™ goes beyond the minimum requirements.

If your vaccine studies have secondary endpoints based on serologic analysis, it is important that your laboratory conduct these assays according to GLP and in a manner compliant with 21 CFR 11. Often vaccine studies may include the collection of esoteric data that comes from University laboratories. If researchers send their esoteric analyses to Sponsors via Excel spreadsheets or other vehicles without clear attribution and password protection and without a clear audit trail, it fails 21 CFR 11 compliance. PDS provides a better approach.

When deployed to your laboratory sites, data will be entered into PDS Express, will be stored on site (as per 21 CFR 312.62), will be uploaded into the central database, and will be available for use as the Sponsor determines. This approach is compliant with all current regulatory guidance. PDS Express also makes the data entry easier and the data transfer process transparent for the Investigator.

Importation of Images

PDS Express was designed from its inception to collect "non-traditional" types of data, beyond standard alpha-numeric data. One of the first vaccine submissions using PDS Express required the importation and cataloging of many hundreds of western blot images. This ability provided the Sponsor with the flexibility they required in study endpoint design while simplifying data collection and organization. PDS Express easily imports your medical binaries (e.g. ECG tracings), digital images (photos, X-ray images, CTs, etc), scanned data, and more.

High performance and better results, even with minimal connectivity

In an ideal world, the best sites for your study will all have cheap, reliable broadband connectivity. Where high-speed connectivity is available, an on-line configuration is simpler and cheaper than engineering a fully replicated system and PDS Express fully supports this design, working from existing on-site computers.



For the real world, the technical design of PDS Express also provides a solution that allows you to accommodate site requirements, rather than forcing the sites to adapt to technology limitations. This flexibility improves protocol compliance while the PDS system ensures regulatory compliance.

Only PDS offers a full on-line approach with the experience and technical sophistication of an FDA-accepted approach that combines both broadband deployments that are fully on-line as well as laptop deployments that are off-line until they replicated with the PDS study database. PDS will tailor the configuration to the individual sites and can mix and match them in any proportion within a single study. This may be crucial for a vaccine study where a third world site could use an off-line version with replication via analog telephone lines, while other sites are better served by an on-line configuration with a central database and on-line data entry. PDS has a proven solution that replicates reliably to a central database.

The PDS Pricing Model

PDS solutions are cost-competitive with paper-based approaches for early stage studies and less expensive than paper for later phase studies. PDS is also usually less costly than other EDC solutions, while offering a better pricing model that supports speed and simplicity for the Sponsor. Most importantly, PDS pricing is transparent, simple to understand, and easy to budget a complete study. Compared to our competitors PDS pricing is for the entire study and not just the initial expense before the change orders begin.

PDS has customized design and pricing approaches for both prophylactic vaccines and for therapeutic vaccines that will help you maximize the results of your next study. Get better visibility of your data. Have better predictability for your costs.

About Phoenix Data Systems:

Phoenix Data Systems, Inc. (PDS) is a leading eClinical technology provider, offering Full Service EDC, a unique combination of electronic data capture, interactive voice response, and clinical data management services. Full Service EDC provides clinical data managers with optimal control to run well-managed studies.

For additional information,
please visit our website at www.phoenixdatasystems.net or call 1-866-PDS-4EDC.