# Data Delivery of INDs

*The route to faster IND preparation requires turning to a data versus document approach.*

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At a time of unprecedented change within the pharmaceutical industry, improved insight into the process and the efficient progression of preclinical discoveries into clinical development projects is critical. Preclinical development is a complex collaboration between diverse scientific disciplines. This process, taking many months to perform—and considerable time to report upon—represents a vital data ecosystem that companies large and small, fully integrated or outsourced, need to understand and use more effectively.

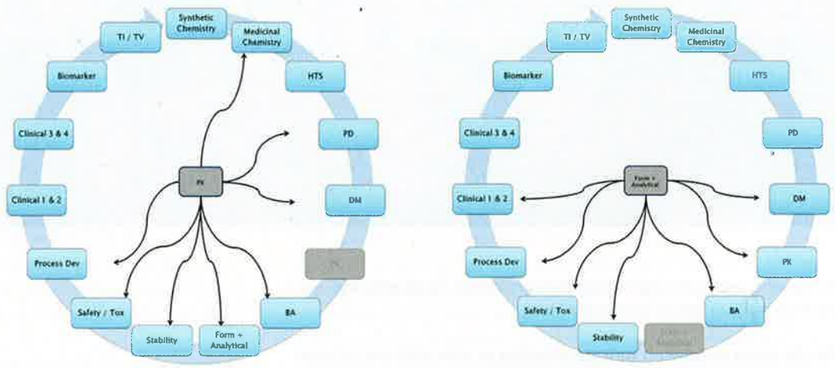
There are three major areas that are vital to improving preclinical development: allowing each group in the community to collaborate via data, to improve quality and speed of process by better use of historical data, and to ease the production and validation of the Investigational New Drug (IND) submission. Major improvements can be made by using an electronic laboratory notebook (ELN) that supports multiple domain-specific workflows, generates rapidly validated data reports, and supports an agreed ontology.

## A data community

Preclinical development is a complex data community, requiring clarity of communication incorporating rich layers of context to be most successful. Each group, whether drug metabolism and pharmacokinetics (DMPK), bioanalytics (BA), formulations/CMC, drug safety, or process development begins their part of the process using multiple data inputs from the other groups (see figure). These inputs affect how candidates will be tested, how results will be interpreted, and can help avoid wasted effort on unnecessary experiments. Scientific challenge of existing data and a clear handover of ideas are necessary at each interface to make sure that the right work is done and the right decisions are made.

## A common language

The use of a common set of terms should be the aim of every data-driven organization. Effective collaboration demands that relevant terms, concepts, and measurables be clearly understood by all. Agreeing on these terms is vital and a long-term driver of efficiency, even if it does require upfront investment in brokering agreements. A common scientific lexicon provides transparency and consistency, the ability to query with confidence across an organization and disciplines—and between contract research organizations or contract manufacturing organizations and their customers—knowing that all the relevant data will be retrieved and enabling effective comparisons to be made. Systems that embed this concept of a common vocabulary allow these terms to be selected and used across multiple workflows, bringing together the community through shared understanding of information.




Each preclinical department should be able to view–from its own perspective–data from many different groups across the organization. In this case, formulations and analytical have a different but overlapping data landscape to pharmacokinetics. (Source: IDBS)

## Single point of truth

Data for IND is produced in a similar manner to a supply chain and can benefit from the well-established concept of the "single point of truth", the definitive datasource that the entire chain uses. In theory, the data section of the IND is a summary version of this but this final document is not usable as a datasource. It is a report, fixed in time, version, and place. It is poorly searchable and is not purposed for integration of data from it with anything else. Supply chains feed off data and need a data-centric approach.

## Data-centric vs. document-centric systems

Preclinical development groups have traditionally communicated and stored their work by documented report. These reports are containers of selected tabular data with varying levels of structure and context. Each report takes time to prepare, check, and approve. All together, report writing consumes up to 25% of users' time (IDBS research). Moreover the reports are difficult to integrate and take significant time to consume. Although this "handover-by-document" process is well understood and provides convenient checkpoints in the overall process, it is not efficient.

In many data-intensive industries, there is a strong movement towards the use of data, not documents, to drive processes. A preferred approach is real-time access to up-to-date data with the ability to build reports on-the-fly for management, milestones, or archiving. This can only be done effectively if the originating data are systemically organized, readily searchable, and stored in a format that is amenable for collating into reports.

## Review by exception and process insight

The growth of Quality by Design (QbD) brings a more systematic approach to improving product quality. It also drives better characterization and monitoring of acceptable variations in processes. Enterprise systems form a foundation to support QbD by providing the data and knowledge management backbone across preclinical development, but still allowing historical data to be compared automatically with current data. This enables predictive models to be built and multivariant analyses to be run, providing vital process insight and improvement.

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Quality assurance frequently presents a considerable bottleneck in the reporting life cycle, as source records must be cross-checked, errors corrected, and reports iteratively updated. Systems that monitor user compliance with approved methods, eliminate manual data transcription, and validate data at the point of capture can greatly simplify downstream quality assurance overhead. Review by exception means results that are outside of approved business rules or historical quality ranges are automatically flagged, providing quality assurance officers with a focus for their efforts. This approach can realize dramatic improvements in throughput.

## IND creation and validation

The IND submission is the product of all this collaboration, effort, and expenditure and is the distillate of all the information derived throughout the process. It is also the key to unlocking a vital first-in-man study. INDs take many months to create, not least because of the requirement to collate, integrate, and then validate the scientific data it holds. To date, this has been produced by an amalgamation of documents, painstaking review, and a requirement to track down scientists for further qualification and validation of data. This is massively inefficient and an obvious area for gaining back vital time.

Here, data-centric information systems make an important difference. For example, with the E-WorkBook from ID Business Solutions Ltd. (IDBS), users can execute a query to pull together experimental and report data and build a data report section for inclusion in an IND. Using hyperlinks embedded in the data report, quality assurance groups can drill back to the original experimental data including calibrations, raw data, calculations, and interpretations to validate the report. This enables savings in resources and time for both the regulatory groups and the scientific disciplines and can turn a process of weeks into one of days.

Many practical, process, and technology improvements are needed to speed the progress of candidates into development. These must result in better use of science and regulatory groups' time, faster, smoother handovers from one preclinical development group to another, and the rapid creation of validated IND submissions. A major contributor to these improvements can be an enterprise software platform that supports the diverse workflows, provides real time process insights, and links the process and the reports together through data. ■

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The authors of the article "A New Roadmap" published in the April issue of *Drug Discovery & Development* have updated the article. The revised, online version of the article can be found on *www.dddmag.com*.