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FierceBiotech IT

EDC brings real time to respiratory trials

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As [reported last week](#), Barcelona-based Almirall, a long-time customer of Perceptive Informatics, has gone back to the well to prep for upcoming trials of respiratory therapeutics. The drugmaker, already a user of Perceptive's IMPACT clinical trial management system and ClinPhone randomization and trial supply management system, will now also be using the DataLabs electronic data capture solution. All three products are part of Perceptive's eClinical offerings.

No clinical trial is easy, but trials for respiratory drugs pose particular challenges. Studies with endpoints coming directly from spirometry devices require reconciling the patient and visit data with corresponding spirometry test data. The solutions provider set up the DataLabs EDC technology to simplify reconciliation tasks and to identify where queries need to be resolved in the case of discrepancies, says Kyle Flickinger, the vendor's director for eClinical solutions, via email.

The objective for Almirall was to cut the information delays that give clinicians an incomplete picture of trial status, and thus sub-optimal data for use in decision-making.

The technology upgrade is intended to give site personnel randomization information in real-time as they enter patient information into the DataLabs EDC system, which also receives automatic imports of RTSM data. The EDC system receives central lab data on a daily basis, and researchers view the data within electronic case report forms.

Flickinger says the solution also aids investigators by flagging values with clinical significance and combining reports containing lab values with other patient data for a trial data overview.