# RDCG CASE STUDY: Real Time Monitoring using CTMS System for IVD study sample collection

## Situation:

Sponsor and Research Dynamics needed to know the demographics of the samples tested for an In-Vitro Diagnostic (IVD) study in real time to ensure that samples met the required demographics as well as other characteristics and were being collected and tested efficiently.

## Challenges:

Demographic data for each sample could not be entered or saved from the lab instrument. Therefore the demographic data were collected on paper CRFs for each sample as the Sponsor decided not to use an EDC system and eCRFS. The challenge was to review the demographics of the samples each day of testing using paper CRFs over the course of collecting and testing thousands of samples.

In addition, the demographics in the CRFS needed to be matched to the samples

## RDCG Actions:

RDCG used their internet-based CTMS system (Clinical Conductor Enterprise) to collect the demographic data in real time in order to make decisions on sample collection and testing to meet the demographic and other sample criteria during the study.

The Testing Site scanned the demographic CRFs into our CTMS system as the CRFs were completed. The CRFs were de-identified and only had a study ID number on each page before they were scanned and uploaded into the CTMS system. RDCG staff reviewed and compiled the data from the scanned CRFs daily to decide based on demographics from the daily CRFs which samples were still needed to be collected and tested.

This CRF data was used to determine demographic and other characteristics of the samples tested to determine which samples were still needed to meet protocol requirements. The actual CRF data was also sent directly to the sponsor for their database and statistical analysis.

CRF sample demographics were matched to the sample by assigning unique numbers to each sample that referenced the patient sample ID on the CRF. This unique number was entered into the instrument for each sample.

## Result:

**The daily review of the paper CRF data allowed for sample collection decisions to be made daily so the collection and testing was completed efficiently with minimum duplicates.**

Key Results:

- Protocol requirements for samples of certain demographics were met efficiently and quickly
- CRFs were available for data review and monitoring on a daily basis from the site.
- Samples were tracked and reviewed daily to assess sample data collected to date.
- Sample tracking on a daily basis determined which specific samples were needed to complete protocol.
- CRFs were also sent to sponsor for entry into their database for statistical analysis of the study results.

 