# AUTOMATION IN

Sarjen Systems Pvt. Ltd.
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# BIOAVAILABILITYBIOEQUIVALENCE TRIALS FOR APPOSITE STUDY CONDUCT AS PER REGULATORY NORMS

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## Brief description:

Clinical Trial and Bioavailability-Bioequivalence (BA and BE) studies are continuously carried out and are increasing in volume to acquire the best available treatment options in the market. These processes involve various steps for a study/trial to be completed and are under strict vigilance by Country Authorities, so as to ultimately ensure the safety of patients/volunteers and quality of data generated.

BizNET-CTM provides a collaborative solution for conducting these trials/studies by exploiting available technology and generate real-time data.

## Scenario at a CRO & Guideline requirements on sampling time points collection:

For a number of Bioavailability and bioequivalence studies, different sample time points need to be captured for the study based on the type of drug products and the study design.

Under varied national and international BA and BE guidance documents followed for studies, sampling and its precise time points have always been emphasized. This includes, but is not limited to:

- Pilot study samples – optimizing sample collection time intervals
- Sample collection and sampling times
- Samples should be withdrawn at appropriate times for ADME kinetics
- Usually, 12–18 samples are recommended including the pre-dose sample (though likely to vary based on several factors)
- Actual time clock for record of withdrawn samples, giving the data for time elapsed related to drug administration
- Plasma concentration and time points should be submitted as a part of PK information in studies
- Likewise, Indian guidelines for Bioavailability and bioequivalence studies also requires documentation (in the BA and BE study report) of the volunteer specific plasma concentrations and time points for test and reference products.

# Problems faced:

A solution was required by the Client to ensure all sample time point requirements as mentioned with respect to applicable guidelines are met with Also, following were the additional yet critical areas of concern:

- Adherence to study protocol
- Maximized utilization of technology to trace actual sample collection points
- Lessened manual intervention (thus reducing chances of errors in process)
- Audit trail of overall sample process in accordance to 21 CFR part 11

These prime concerns were implemented and turned out to be key benefits of the application as they not only sufficed the Client's requirements but also assured data integrity and quality.

# Solution:

BizNET application has provided a flawless solution through automation.

By using this system, sampling time points can be scheduled in application based on first reference time point and all the time points would then follow.

It became highly convenient for the user where all the time points, pre-dose and post–dose were auto calculated, simply gunning the generated sample barcodes was required for each time point.

Based on study protocol specifications, deviation of sample time points collection by ± 1 minutes (or as the case may be) is recorded with justification by user.

This called for robust identification at three check points-

- Right sample
- Right volunteer/patient,
- Correct scheduled time point

# The salient benefits include:

- Accurate clock time for sample drawn
- System generated alert for above mentioned three check points in case any deviation is noticed (preventing erroneous data entry from hampering the trial process)
- Accurate sample analysis against each collected time point
- Audit trail is generated for absolute transparency of the process followed and its record maintenance for future audits/inspections

# Reaping results:

Advanced, user friendly methodology is adapted and the data generated is accurate, validated and adheres to applicable BA-BE guidance.

Its direct interface with the Sample collection page minimizes data entry of the phlebotomist allowing them to concentrate more on the process instead of sheer documentation.

# Process improvisation till excellence:

The technology was developed further for safety samples, pharmacodynamics samples and dosing activity to attain utmost credibility in the data recorded for CT/BABE studies.

# References:


- *USFDA draft guidance "Guidance for Industry: Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs — General Considerations"*
- *Indian BA and BE guidance "Guidelines for Bioavailability and Bioequivalence Studies"*


# Contact Us:


Corporate Communication corp.comm@sarjen.com


## Websites:

Company Website www.sarjen.com
Adverse Event Reporting Tool pvnet.sarjen.com
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