Enabling Patient Centricity in Clinical Development through at Home Sample Collection

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Traditional approaches for measurement of drug exposure in clinical trials involves having the patient travel to a clinical site for collection of venous blood. This puts a burden on the patient while also limiting the opportunities for assessment of drug exposure or other measurements to these clinical visits. The ability to collect samples at home would provide a more patient centric approach. At home collection would provide benefit for 1) disease areas associated with episodic events (e.g. asthma, migraine, etc.), 2) long half-life compounds, 3) assessment of adherence, 4) developing understanding of adherence patterns for new dosing regimens (i.e. QWeekly, QMonthly), 5) more frequent assessment of biomarkers of efficacy and toxicity.

At home collection requires technology that is both convenient for the patient to use while providing a high quality sample for laboratory analysis and regulatory acceptance. Dried blood sampling has evolved from early use in neonatal screening programs to become a high performance analytical tool capable of providing samples suitable for quantitative analysis in clinical development. Recent efforts have focused on volumetric approaches to sample collection coupled with single use, integrated lancet devices that provide a convenient, easy to use collection experience (**Figure 1**). Addition of automated data collection for date and time of sampling, as well as sample temperature during shipping, will ensure accurate recording of sampling time and sample integrity. Data will be presented from clinical trials piloting the use of at home sample collection highlighting the ability to collect pharmacokinetic data equivalent to data collected during traditional clinical visits.

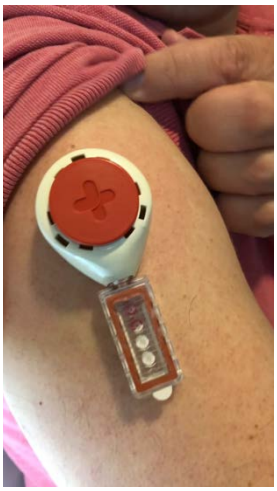

Figure 1. Tasso Hemolink with volumetric adsorptive microsampling for dried blood collection.