CLINICAL STUDY PROTOCOL

Title:	Phase 1 Study Evaluating Technologies for Point-of-Care Blood Collections in Support of Decentralized Outpatient Assessments in Pandemic and Clinical Trial Settings
Short title:	Evaluating Technologies for Point-of-Care Blood Collections by Patients
Protocol number:	5309/0024
Study phase:	Phase 1
Device:	Tasso+™ Device (third generation)
Sponsor/Principal Investigator:	Resilience Government Services, Inc. Jordan Bauers, PharmD 13200 NW Nano Court, Alachua, FL 32615 email: Jordan.Mitchell@resilience.com Fax: +1 888 551 1691
Funding mechanism:	Department of Defense (DoD) Joint Program Executive Office (JPEO) Agreement #W911QY-20-9-0007
Contract research organization:	ICON plc Corporate Headquarters South County Business Park Leopardstown, Dublin 18 Ireland Phone (IRL): +353 1 291 2000 Phone (US): +1 215 616 3000 Fax: +353 1 247 6260
Protocol version and date:	Version 3.0, 17 Jan 2025

The study will be performed in compliance with this protocol (clinical investigation plan), in accordance with the Note for Guidance on International Council for Harmonisation guidelines on Good Clinical Practice (ICH GCP) Harmonised Tripartite Guideline E6 (R1)/Integrated Addendum E6 (R2); US FDA CFR (Title 21 Parts 50, 56, 312).

PROTOCOL SIGNATURE PAGE – SPONSOR

This protocol (5309/0024, Version 3.0, 17 Jan 2025) has been reviewed and approved by the representative(s) listed below. Any modification of the protocol must be agreed upon by the Sponsor and the Investigator and must be documented in writing.

Jordan Bauers, PharmD
Resilience Government Services, Inc.
13200 NW Nano Court, Alachua, FL 32615
email: Jordan.Mitchell@resilience.com
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Jordan Bauers	Sponsor
Print Name	Title
Signed by: Jordan Bauers Signer Name: Jordan Bauers Signing Reason: I approve this document Signing Time: 21-Jan-2025 | 14:00:53 GMT 4859D5F447734BE2B4BA7C29E107A40E	21-Jan-2025 | 14:01:28 GMT
Signature	Date

PROTOCOL SIGNATURE PAGE – CONTRACT RESEARCH ORGANIZATION

This protocol has been reviewed and approved by the representative(s) listed below. Any modification of the protocol must be agreed upon by the Sponsor and the Investigator and must be documented in writing.

ICON representative(s):

Robert Spitz	Medical Monitor
Print Name	Title
Signed by: Robert Spitz Signer Name: Robert Spitz Signing Reason: I approve this document Signing Time: 21-Jan-2025 | 20:29:24 GMT E8A7512DA3FD49D988314663EBD4148D	21-Jan-2025 | 20:29:58 GMT
Signature	Date

PROTOCOL SIGNATURE PAGE – INVESTIGATOR

I have read this protocol, which has been agreed to by Resilience Government Services, Inc. (Jordan Bauers, PharmD) and given approval/favorable opinion by the IRB/IEC, and I agree that it contains all necessary details to conduct this study as described. I will provide copies of the protocol and any amendments to all study personnel under my supervision and provide access to all information provided by Resilience Government Services, Inc. (Jordan Bauers, PharmD) or his specified designees. I will discuss the material with the study personnel to ensure that they are fully informed about the study.

I understand that information contained in or pertaining to this protocol is confidential and should not be disclosed, other than to those directly involved in the execution or the ethical review of the study, without written authorization from Resilience Government Services, Inc. (Jordan Bauers, PharmD). It is, however, permissible to provide information to a participant in order to obtain consent.

I agree to conduct this study according to this protocol and to comply with its requirements, subject to ethical and safety considerations and guidelines, and to conduct the study in accordance with the Declaration of Helsinki, ICH GCP, and applicable regional regulatory requirements.

I agree to comply with the procedures described for data recording and reporting and to permit monitoring and auditing by Resilience Government Services, Inc. (Jordan Bauers, PharmD), and inspection by the appropriate regulatory authorities.

I agree to make my participants' study records available to Resilience Government Services, Inc. (Jordan Bauers, PharmD), his personnel, his representatives, and relevant regulatory authorities in order to verify data that I have entered into the electronic case report forms (eCRFs). I will retain the study-related essential documents until Resilience Government Services, Inc. (Jordan Bauers, PharmD) indicates that they are no longer needed. I am aware of my responsibilities as an Investigator as provided by Resilience Government Services, Inc. (Jordan Bauers, PharmD).

I understand that Resilience Government Services, Inc. (Jordan Bauers, PharmD) may decide to suspend or prematurely terminate the study at any time for whatever reason; such a decision will be communicated to me in writing. Conversely, should I decide to withdraw from execution of the study, I will communicate my intention immediately in writing to Resilience Government Services, Inc. (Jordan Bauers, PharmD).

Investigator (Name, Title, Institution):

Signature	Date

SERIOUS ADVERSE EVENT CONTACT INFORMATION

In the event of a serious adverse event (SAE), the Investigator will send a safety report form immediately (no later than 24 hours) after becoming aware of the SAE to:

ICON Pharmacovigilance and Safety Services (PVSS) Americas

Phone: +1 888 426 8801

Fax: +1 215 616 3096

Email: icon-mads@iconplc.com

PROTOCOL SUMMARY

Protocol number: 5309/0024

Protocol title: Phase 1 Study Evaluating Technologies for Point-of-Care Blood Collections in Support of Decentralized Outpatient Assessments in Pandemic and Clinical Trial Settings

Short title: Evaluating Technologies for Point-of-Care Blood Collections by Patients

Sponsor/Principal Investigator (PI): Resilience Government Services, Inc. (Jordan Bauers, PharmD) 13200 NW Nano Court, Alachua, FL 32615; email: Jordan.Mitchell@resilience.com; Fax: +1 888 551 1691

Funding: Department of Defense, Joint Program Executive Office, Agreement #W911QY-20-9-0007

Study phase: Phase 1

Clinical sites: It is planned to recruit up to 5 sites in the US

Objectives and endpoints:

Primary objective	Primary endpoints
To assess the Tasso+™ performance (sample integrity, testing accuracy, and reliability)	• Percentage of overall Tasso+™/serum separator tube (SST) samples collected that are with adequate volume and without moderate or gross hemolysis on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined • Percentage of overall Tasso+™/ ethylenediaminetetraacetic acid (EDTA) samples collected that are with adequate volume, without moderate or gross hemolysis, and without clotting on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined
	• Correlation of SARS-CoV-2 serology between venipuncture and Tasso+™/SST or Tasso+™/EDTA samples on Day 1 for each cohort • Correlation of each chemistry analyte between venipuncture and Tasso+™/SST samples on Day 1 for each cohort
	• Percentage of Tasso+™ device failures from Day 1 to Day 57 defined as (i) failure in activation of the lancet; (ii) lack of any blood collection within 5 minutes; (iii) incorrect attachment of the capillary collection tube to the device; (iv) damage to the device or the capillary collection tube upon handling; (v) lack of maintained seal between the device and the skin surface of the participant; or (vi) incomplete trigger of the button (not fully pressing the button once the Tasso+™ device is sealed to the skin surface)

Secondary objectives	Secondary endpoints
To evaluate Tasso+™ user experience (safety, tolerability, and usability)	• Percentage of eligible participants who experience solicited local adverse events (AEs) including pain, tenderness, redness, swelling, or bruising within 7 days of Tasso+™ administration • Percentage of eligible participants who experience unsolicited AEs within 28 days of Tasso+™ administration • Percentage of eligible participants who experience a related Grade 3 AE, a related Grade 4 AE, a related AE leading to study discontinuation, or a related SAE within 28 days of Tasso+™ administration
	• Percentage of eligible participants who complete last Tasso+™ administration (Day 57)
	• Ease of use as assessed by the participant completing the Tasso questionnaire immediately following administration (on Days 1, 29, and 57) and on Day 85
To perform surveillance for SARS-CoV-2 infection	• Percentage of eligible participants with a positive nasopharyngeal swab for SARS-CoV-2 polymerase chain reaction (PCR) on Day 1 • Percentage of eligible participants seroconverting to SARS-CoV-2 between Days 1 and 57
Exploratory objective	**Exploratory endpoint**
To evaluate the impact of prior training on subsequent Tasso+™ administrations	• Descriptive analyses of proctor-supported and proctor-unsupported Tasso+™ administrations on Day 57 using each of the following endpoints: o Sample integrity o Reliability o Safety o Usability

Study design:

This is a Phase 1, multicenter, observational, study that will evaluate the Tasso+™ device in approximately 200 male or female adult participants in an outpatient setting who are healthy or in well-compensated health at up to 5 US sites. They will be randomized in a 2:1 ratio between Cohorts A and B. Tasso+™ blood samples of participants randomized to Cohort A will be shipped to the Central Laboratory where they will be centrifuged and aliquoted. However, Tasso+™ blood samples of participants randomized to Cohort B will be centrifuged and aliquoted at the Site prior to shipping to the Central Laboratory, following the same approach used for venipuncture blood samples.

Baseline information regarding COVID-19 experience will be elicited to include prior vaccination(s) and prior or new illness consistent with COVID-19. The SARS-CoV-2 infection surveillance during the study will comprise SARS-CoV-2 PCR screen at study entry, regular symptom checks at each visit and assessment for SARS-CoV-2 seroconversion between Day 1 and Day 57.

Training on the Tasso+™ will consist of a detailed Instruction for Use (IFU) and online video training. In addition, when administering the Tasso+™ remotely, participants will receive proctor-support on Day 29 (and if requested, on Day 57) during working hours, the intent being to guide the participant through the process and to help troubleshoot should any difficulties be encountered.

Collection: Participants, once trained on the Tasso+™ device, will perform two Tasso+™ self-

administrations (preferably collecting a SST tube from left upper arm and an EDTA tube from right upper arm) on each of Days 1, 29 and 57. Participants will complete a Tasso questionnaire (available in eDiary) immediately following each Tasso+™ administration (Days 1, 29 and 57) and on Day 85 to document the user experience. Additionally, the participants will complete a Symptom questionnaire (available in eDiary) for a 28-day period following each Tasso+™ administration to report symptoms. Safety data collection will be solicited from each participant for the first 7 days after each Tasso+™ administration and unsolicited AEs will be captured for a 28-day period after each Tasso+™ administration.

On Day 1, in the Clinic, the blood collected by the participant (site-supervised) using the Tasso+™ and the blood collected by a qualified healthcare professional (HCP) using venipuncture will be compared with respect to testing accuracy for SARS-CoV-2 serology and for selected chemistry analytes. For Cohort A participants, the venipuncture collection tube(s) will be centrifuged and aliquoted prior to shipping, while the Tasso+™ capillary collection tube will be centrifuged and aliquoted after shipping to the Central Laboratory. For Cohort B participants, both Tasso+™ and venipuncture tubes will be centrifuged and aliquoted prior to shipping to the Central Laboratory. Tasso+™ and venipuncture collections will be both packed and shipped by the HCP during this visit.

On Day 29, blood will be collected remotely by the participant (proctor-supported) using the Tasso+™ device in a decentralized setting, according to provided training and instructions. The Tasso+™ tubes will be both packed and shipped by the participant for this visit.

On Day 57, blood will be collected remotely by the participant (proctor-supported as requested) using the Tasso+™ device in a decentralized setting, according to provided training and instructions. While assistance will be available to the participant during this visit, it is of interest to know whether the prior trainings on Tasso+™ administration prove adequate for this subsequent administration. The Tasso+™ tubes will be both packed and shipped by the participant for this visit.

Packaging, and shipment: Participants, once trained, will self-administer the Tasso+™ in the Clinic (site-supervised) on Day 1, while the Site will centrifuge and aliquot (Cohort B samples only), and package and ship the samples to the Central Laboratory (see Figure 1). The participant will self-administer the Tasso+™ subsequently remotely at home, ie, at home or a suitable remote location (proctor-supported on Day 29 and, as requested on Day 57). Participants will package and ship the samples to the Central Laboratory.

Sample processing and testing: After samples have been received by the Central Laboratory, both SST and EDTA capillary collection tubes will be centrifuged and aliquoted (Cohort A samples only) for testing by the Central Laboratory.

The parameters to be used to assess sample integrity (both SST and EDTA samples) will be measured/assessed by the Central Laboratory and will comprise blood volume, hemolysis, and for EDTA alone, the determination of presence of clotting.

The parameters to be used to assess the testing accuracy using Tasso+™ capillary-drawn samples when compared to those collected by venipuncture will include SARS-CoV-2 serology (SST and EDTA samples) and selected chemistry analytes (SST samples only).

The final Visit (Day 85) will be conducted to complete the final Symptom questionnaire and the Tasso+™ questionnaire.

Study duration:

Each participant's study involvement will last for approximately 85±3 days.

The start of the study will be the date the first participant provides informed consent, and the end of the study will be the date the last participant receives the final assessment.

Planned number of participants: It is planned to enroll approximately 200 participants.
It is planned to randomize approximately 133 participants into Cohort A and approximately 67 participants into Cohort B.

Target population:

Participants aged 18 years or older who are considered healthy or in well-compensated health as determined by the Investigator based on medical history, concomitant medications, and physical examination (including vital signs) would satisfy the inclusion criteria for study eligibility. Regardless of the pregnancy test result (positive or negative), the participant will remain eligible for study participation. Thus, the participants who are deemed pregnant by urine pregnancy test at Screening remain eligible.

A participant who meets any of the following exclusion criteria will not be eligible for participating in the study:

1. Medical history, or physical examination (including vital signs) findings, that suggest to the Investigator that the participant has undiagnosed or untreated medical condition(s) that could confound the AE evaluation and thereby undermine the study objectives.
2. Any known medical history of infection with HIV (CD4<200 and/or detectable viral load within the prior 3 months), hepatitis B (positive HBsAg), or hepatitis C (positive hepatitis C virus antibody).
3. Chronic illness for which a participant's immune system is suspected by the Investigator to be impaired or altered, such as cancer, autoimmune conditions, and diabetes.
4. Participation in another investigational study within 30 days of time of consent or plans to do so during the course of this study.
5. Large tattoos or skin eruptions overlying either of the deltoid muscles that could confound the monitoring for local reactogenicity following Tasso+™ administrations.
6. Use of systemic immunomodulatory therapy, including oral corticosteroids, within the past 6 months; or planned use of medications or nutritional supplements known to or which potentially could affect organ function within 30 days prior to screening until end of study.
7. Acute illness within 14 days prior to device use unless it is determined by the Investigator that the illness is mild in severity and unlikely to progress.
8. Of limited legal capacity.
9. Any condition (including suspected alcohol- or drug-related addiction) that precludes adequate understanding, cooperation, and/or compliance with study procedures or any condition that could pose a risk to the participant's safety per Investigator judgment.

Device:

Name: Tasso+™ Device (third generation)

Description: Tasso+™ device lancet is an FDA 510(k)-cleared Class II medical device in the US. The Tasso+™ kits are designed to collect up to 600 µL of blood within 5 minutes.

Statistical methods:

Descriptive statistics will be used to summarize primary endpoints, ie, device performance (sample integrity, testing accuracy and reliability), as well as secondary endpoints, ie, user experience (safety, tolerability, and usability) and seroconversion.

The analysis set for the primary endpoints will be the full analysis set (FAS). Where appropriate the analyses will be repeated for the per protocol analysis set (PPS).

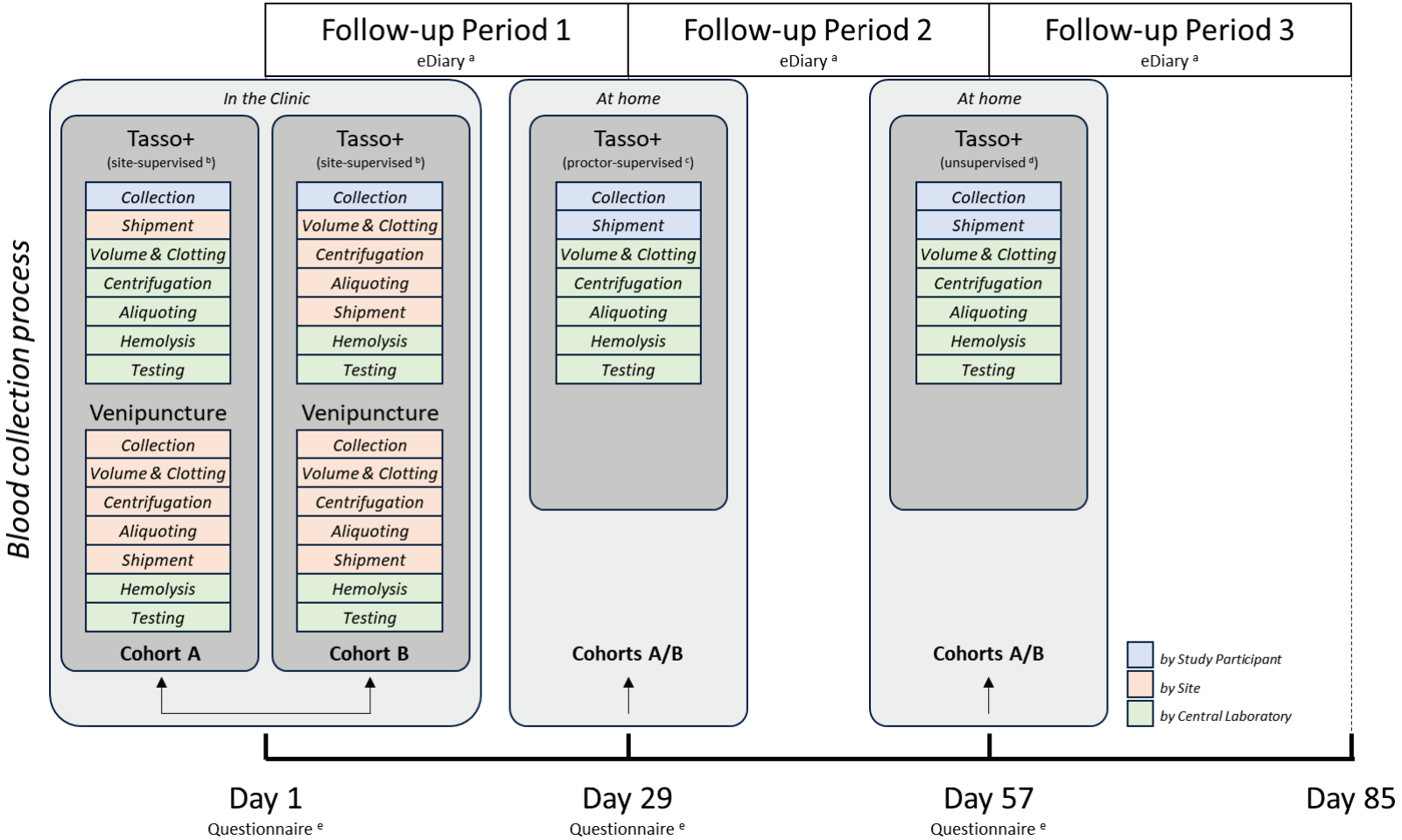
The details of all analyses will be specified in a separate statistical analysis plan (SAP).

Safety assessments will be analyzed using the safety analysis set (SAS).

Protocol version and date: Version 3.0, 17 Jan 2025

STUDY SCHEMATIC

Figure 1 Study Schematic



Footnotes:

a eDiary will be completed during each follow-up period to collect safety data (Symptom questionnaire) and user experience (Tasso questionnaire).

b Day 1 collection to be site-supervised; venipuncture samples (SST and EDTA tubes) and Cohort B Tasso+™ samples (SST and EDTA capillary collection tubes) to be centrifuged and aliquoted by the Site before shipping; venipuncture samples (SST and EDTA tubes) and Tasso+™ samples (SST and EDTA capillary collection tubes) to be shipped to Central Laboratory by the Site; Cohort A Tasso+™ samples (SST and EDTA capillary collection tubes) to be centrifuged and aliquoted by the Central Laboratory upon receipt.

c Day 29 collection to be remotely proctor-supported (during working hours); Tasso+™ samples (SST and EDTA capillary collection tubes) to be packaged and shipped to Central Laboratory by the participant.

d Day 57 collection to be remotely proctor-supported (during working hours), as requested; Tasso+™ samples (SST and EDTA capillary collection tubes) to be packaged and shipped to Central Laboratory by the participant.

e eDiary (Tasso questionnaire) will be completed immediately following each Tasso+™ administration and on Day 85 to document the user experience.

SCHEDULE OF ASSESSMENTS

Table 1 Schedule of Assessments

Assessments	Visits[a]			
	Visit 1	Visit 2	Visit 3	Visit 4
Study Day (±visit window)	**1**	**29±3**	**57±3**	**85±3**
In-clinic	X			
Decentralized (eg, home)[b]		X	X	X
Proctor session[c]		X[c]	(X)[c]	
Training	X[c]	X[c]	(X)[c]	
Informed consent (eConsent)	X			
Demographics	X			
Medical history[d]	X			
Concomitant medication	X	X	X	X
Vital signs[e]	X			
Physical examination[f]	X			
Pregnancy urine test (females only)	X			
Eligibility check	X			
Randomization (IVRS)	X			
COVID-19 symptom screen[g]	X	X	X	X
Nasopharyngeal swab for SARS-CoV-2 PCR[h]	X			
Tasso+™ collection SST capillary collection tube (left upper arm preferred) EDTA capillary collection tube (right upper arm preferred)	 X[il] X[il]	 X[jl] X[jl]	 X[kl] X[kl]	
Venous blood collection SST tube EDTA tube	 X[im] X[im]			

Assessments	Visits[a]			
	Visit 1	Visit 2	Visit 3	Visit 4
Study Day (±visit window)	**1**	**29±3**	**57±3**	**85±3**
eDiary				
Tasso questionnaire (user experience)	X	X	X	X
Symptom questionnaire (AEs/SAEs)[n]	X	X	X	X

AE=adverse event; EDTA=ethylenediaminetetraacetic acid; IFU=instruction for use; IVRS=interactive voice response system; HCP=healthcare professional; PCR=polymerase chain reaction; SAE=serious adverse event; SST=serum-separator tube

Footnotes:

a If a participant withdraws from the study early, the assessments planned for the last follow-up/end of study Visit should be completed at the time of withdrawal.

b Defined as any remote location of convenience for the participant where the administration can be done with appropriate technique in a clean environment where samples can be packaged for shipment.

c When administering the Tasso+™ remotely, participants will receive proctor-support on Day 29 (and as requested, on Day 57), the intent being to guide the participant through the process and to help troubleshoot should any difficulties be encountered. Proctor sessions will be prescheduled by the Site to take place during working hours. Training will be performed on Day 1 (by Site) and Day 29 (by Proctor). Training on Day 57 should be performed only if requested by the participant. Training may include detailed IFU and online video training (see Section 7.4 and IFU provided separately). While assistance will be available to the participant during Day 57 Visit, it is of interest to know whether the prior trainings on Tasso+™ administration prove adequate for this subsequent administration.

d Includes COVID-19 illness/vaccine history details (if available).

e Vital signs include heart rate, systolic and diastolic blood pressure, respiratory rate, SpO2 by pulse oximetry, and body temperature (taken by ear/tympanic/temporal, oral, or forehead method). The assessment of heart rate and blood pressure will be conducted in the supine position after a minimum rest period of 5 minutes.

f Physical examination includes general appearance, skin, eyes, ears, nose, throat, head and neck, heart, chest and lungs, abdomen, extremities, lymph nodes, musculoskeletal, neurological, and other body systems, if applicable, for describing the status of the participant's health.

g The development of any COVID-19 symptoms should prompt the participant to contact the Investigator via provided Site's phone number.

h Nasopharyngeal swab for SARS-CoV-2 PCR will be performed and resulted by the Site.

i Day 1 collections: venipuncture samples by HCP (SST and EDTA tubes) and Tasso+™ samples by participant (SST and EDTA capillary collection tubes; Cohort B only) to be centrifuged and aliquoted by the Site before shipping; venipuncture samples by HCP (SST and EDTA tubes) and Tasso+™ samples by participant (SST and EDTA capillary collection tubes) and to be shipped to Central Laboratory by the Site.

j Day 29 collection remotely proctor-supported (during working hours); Tasso+™ samples (SST and EDTA capillary collection tubes) to be packaged and shipped to Central Laboratory by the participant.

k Day 57 collection remotely proctor-supported, as requested (during working hours); Tasso+™ samples (SST and EDTA capillary collection tubes) to be packaged and shipped to Central Laboratory by the participant.

L Tasso+™ samples will be tested by Central Laboratory. Assessments include (by order of priority):
- Volume measurement (SST and EDTA capillary collection tubes), hemolysis (SST and EDTA capillary collection tubes), and evidence of clotting (EDTA capillary collection tube only).
- Chemistry analytes (SST capillary collection tube): sodium, potassium, chloride, blood urea nitrogen, creatinine, glucose, phosphate, uric acid, and C-reactive protein.
- Serology (SST and EDTA capillary collection tubes); any participant who is positive for IgG Nucleocapsid assay for either capillary matrix (SST or EDTA) will be considered positive.

m Venipuncture samples will be tested by Central Laboratory. Assessments include:
- Chemistry analytes (SST tube): sodium, potassium, chloride, blood urea nitrogen, creatinine, glucose, phosphate, uric acid, and C-reactive protein.
- Serology (SST and EDTA tubes); any participant who is positive for IgG Nucleocapsid assay for either matrix (SST or EDTA) will be considered positive.

n Including training for eDiary on Visit 1. Participant can report any AE in the eDiary (Symptom questionnaire). Safety data collection will be solicited from participant for the first 7 days after Tasso+™ device administration, and unsolicited AEs will be captured for the full 28-day period after each administration.

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LIST OF ABBREVIATIONS

ADE	adverse device effect
AE	adverse event
CSR	clinical study report
DCT	decentralized clinical trial
DoD	US Department of Defense
EDC	electronic data capture
EDTA	ethylenediaminetetraacetic acid
FAS	full analysis set
GCP	Good Clinical Practice
HCP	healthcare professional
HJF	Henry M. Jackson Foundation
IB	investigator brochure
ICH	International Council for Harmonisation
IFU	instruction for use
IRB	institutional review board
IVRS	interactive voice response system
JPEO	Joint Program Executive Office
PCR	polymerase chain reaction
PI	Principal Investigator
PPS	per protocol analysis set
QTL	quality tolerance limits
SADE	serious adverse device effect
SAE	serious adverse event
SAP	statistical analysis plan
SOP	standard operating procedure
SAS	safety analysis set
SST	serum-separator tube
TEAE	treatment-emergent adverse event

1 INTRODUCTION AND RATIONALE

1.1 Introduction

1.1.1 Background

The COVID-19 pandemic has spurned the urgent need for SARS-CoV-2 testing and clinical trials to advance both vaccines and antivirals to rapidly achieve control of the pace of viral transmission and the dramatic toll on human lives worldwide.

SARS-CoV-2 testing has oftentimes required that an ill patient (during the pandemic) or study participant (in the context of a clinical trial) travels to a clinic, remains in line or in a waiting room, and risks transmitting SARS-CoV-2 or another pathogen to clinic personnel and other patients. Moreover, FDA has recognized that the COVID-19 public health emergency may impact the conduct of clinical trials of medical products, leading to difficulties in meeting protocol-specified procedures, including adhering to protocol-mandated visits and laboratory/diagnostic testing (FDA, 2021).

Furthermore, in May 2023, the draft guidance for decentralized clinical trials (DCTs) issued by FDA has recognized the potential of DCTs to expand access to more diverse patient populations and improve trial efficiencies. Indeed, by enabling remote participation, DCTs may enhance convenience for trial participants, reduce the burden on caregivers, and facilitate research on rare diseases and diseases affecting populations with limited mobility or access to traditional trial sites. This may help improve study participant engagement, recruitment, enrollment, and retention of a meaningfully diverse clinical population (FDA, 2023).

Nevertheless, the monitoring of the investigation must be ensured, based on a risk assessment, in order to assess protocol compliance and data quality and integrity. Indeed, the variability and precision of the data obtained in a DCT may differ from the data in a traditional site-based clinical trial. Remote assessments may differ from on-site assessments, particularly when trial participants are responsible for performing their own physiological tests (eg, home spirometry). Similarly, assessments performed by local healthcare professionals (HCPs) as part of routine clinical practice (eg, evaluation of symptoms) may also be more variable and less precise than assessments conducted by dedicated trial personnel (FDA, 2023).

Enabling technologies that would allow for the collection of blood and other diagnostic samples at the point-of-care by the patient/participant while at home could potentially offer several benefits, eg, improved patient/participant convenience and comfort, early diagnostic sampling (and thereby potentially early diagnosis), greater participant study compliance (especially for pharmacokinetic and biomarker research endpoints), and relief of phlebotomy-related bottlenecks while reducing any potential transmission risks. Examples include self-collected dried blood spots used for serological screening of sexually transmitted infections to better reach hidden, high-risk populations (van Loo et al., 2017) or for routine doping controls (Fedoruk, 2020). The Tasso+™ lancet is an

enabling technology that is an FDA 510(k)-cleared Class II medical device that permits a potentially favorable blood collection experience in remote settings.

Thus, Resilience Government Services, Inc. (Jordan Bauers, PharmD) is conducting a study in collaboration with the US Department of Defense (DoD) Joint Program Executive Office (JPEO), and the Henry M. Jackson Foundation (HJF) with the aim of supporting telemedicine strategies and virtual clinical trials. The objective of the study is to evaluate the use of the Tasso+™ blood collection device in the clinic and in a decentralized setting (eg, home) with respect to device performance (sample integrity, testing accuracy, and reliability) and user experience (safety, tolerability, and usability), during a SARS-CoV-2 infection surveillance study.

1.1.2 Investigational Medical Device

Tasso, Inc has developed the Tasso+™ blood collection device that enables the convenient collection of blood by a lay person (eg, patient or study participant) under the supervision of an HCP.

The Tasso+™ blood collection kit comprises the collection device (called the Tasso+™), an FDA 510(k)-cleared Class II medical device, and a capillary collection tube that allows for the storage of the blood in a liquid format in different matrices (Table 2).

Table 2 Tasso+™ Kit Configurations

Product Kit Name	Tube Type	Color	Blood Collection Volume	Blood Collection Additive
Tasso+™/EDTA	K_2 EDTA	lavender	250-500µL	K_2 EDTA
Tasso+™/SST	Serum Separator	gold	400-600µL	Clot Activator with Gel
Tasso+™/LH	Lithium Heparin	green	200-400µL	Lithium Heparin
Tasso+™/PST	Plasma Separator	light green	400-600µL	Lithium Heparin with Gel

EDTA=ethylenediaminetetraacetic acid; LH=lithium heparin; PST=plasma separator tube; SST=serum separator tube

In the present study, Tasso+™ blood collection device (third generation) will be used as the Investigational Medical Device along with the Tasso+™/ethylenediaminetetraacetic acid (EDTA) kit and Tasso+™/serum separator tube (SST) kit (Table 2).

The Tasso+™ device is designed to safely, conveniently, and reliably collect blood without the need of a trained phlebotomist or HCP while minimizing pain and discomfort to the patient or study participant. The Tasso+™ is a sterile, disposable, capillary blood collection device, including a lancet assembly, that is designed to allow the attachment of a sample tube to receive the collected capillary blood. The collection device is compatible with existing capillary collection tubes on the market (such as the BD microtainers®) as well as customized Tasso tubes.

The Tasso+™ lancet is an FDA 510(k)-cleared Class II medical device in the US (Tasso, Investigator Brochure, September 2023). The Tasso+™ kits are designed to collect capillary blood volumes ranging from 250 to 600 µL within a 5-minute period.

1.1.3 Previous Clinical Use

The Tasso+™ device has been tested in internal and external studies to measure the blood volumes collected and the user experience. Overall, a total of at least 420 participants have been recruited to date, either to use Tasso+™ device in studies in-clinic (blood collection by an HCP) or in a decentralized setting (blood self-collection by a participant at a remote location of convenience). These studies have aimed to measure sample volume, user perception, and user pain. Following the collection, the user is asked to complete a questionnaire assessing the frequency they would be willing to use the Tasso device, any associated pain, and their blood collection method preference (Tasso, Investigator Brochure, September 2023).

Overall, among 420 participants, on a scale of 0-10 (zero being no pain and 10 being the most imaginable pain), 67% of participants reported feeling no pain, 26% of participants reported pain of 1, 5% reported pain of 2, and 2% of participants reported feeling pain at a 3 or higher with 5 being the highest reported pain. Ninety-five percent of all participants reported to prefer the Tasso+™ blood collection method to venipuncture and finger stick, and 95% of participants reported they would be willing to use the Tasso device at least monthly (Tasso, Investigator Brochure, September 2023).

Recently, a multi-center, unblinded, longitudinal observational study of enabling technologies for COVID-19 surveillance (including the Tasso) was conducted with the objective to provide surveillance through enabling technologies to describe physiological parameters, symptoms, respiratory fluid virus levels, and host immune and inflammatory responses in enrolled subjects (JPEO-003, Summary of Results, 2022).

Overall, 62 participants (52 with mild to moderate COVID-19 and 10 healthy controls) were enrolled at 2 clinical sites in the US beginning in July 2021 and completing follow-up in January 2022. The age of participants ranged from 18 to 90 years in the COVID-19 group (57.7% female) and from 18 to 53 years in the Control group (60% female). Median age in both groups was 30 years. In the COVID-19 group, 18 of 52 participants (34.6%) had previously received COVID-19 vaccine; 7 of 10 in the Control group (70.0%) had previously been vaccinated for the disease. The days from last vaccine dose to enrollment ranged from 21 to 319 days (median 236.5) in the COVID-19 group and from 71 to 305 days (median 193) in the Control group.

Regarding accuracy of Tasso sample against venous sample: control group participants were uniformly antibody positive at all visits in tests performed with venous whole blood or Tasso whole blood. For COVID-19 group participants, 27/48 (56.2%) were positive on Day 1, with progressive increases in positivity rate at each visit to 48/49 (98.0%) on Day 29. Similar results were obtained using Tasso whole blood, but the antibody positivity rate and median antibody cutoff values were lower with Tasso whole blood than with venous whole blood (Table 3).

Table 3 Summary of LightDeck Antibody Results (Venous Whole Blood vs Tasso Whole Blood) (JPEO-003, Summary of Results, 2022)

	COVID-19 group (n=49)			Control group (n=10)		
	Day 1	Day 4	Day 8	Day 1	Day 4	Day 8
Number of Tests Run, n (%)		48 (98.0)			10 (100.0)	
Venous Whole Blood, n (%)						
Negative (non-reactive)	21 (43.8)	14 (28.6)	5 (10.4)	0 (0.0)	0 (0.0)	0 (0.0)
Positive (reactive)	27 (56.3)	35 (71.4)	43 (89.6)	10 (100.0)	10 (100.0)	10 (100.0)
TASSO Whole Blood, n (%)						
Negative (non-reactive)	21 (43.8)	17 (35.4)	7 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)
Positive (reactive)	27 (56.3)	31 (64.6)	42 (85.7)	10 (100.0)	10 (100.0)	10 (100.0)

Regarding safety, 4 total participants (6.5%) from the COVID-19 group (3 of 52 participants [5.8%]) and the Control group (1 of 10 participants [10%]) experienced solicited adverse events (AEs). In more detail, 2 participants experienced mild skin irritation from the monitoring skin patch, which resolved without sequelae; 1 participant had a severe paranasal sinus discomfort; and 1 participant had severe chills. To note, the later 2 AEs (chills and paranasal sinus discomfort) were not considered to be related to the study procedures, as per the site investigator. There were no SAEs in the study. All solicited treatment-emergent AEs (TEAEs) were of mild or moderate severity except for one from the COVID-19 group, which was rated as severe by the investigator. There were no severe or life-threatening AEs. No subjects discontinued the study due to AEs, and no concomitant medications were needed to treat any AEs. No participant had AEs that were considered to be related to study treatment. There were no SAEs, medically attended AEs, or pregnancies reported.

Currently, the third generation of Tasso+™ is being used as an FDA 510(k)-cleared Class II medical device. Based on an e-mail communication with Tasso, from June to August 2023, more than 40,000 third generation Tasso+™ devices have been utilized. Overall, during this period, the following customer feedback has been compiled regarding the use of the Tasso+™ device: no blood collected (n=8); insufficient volume collected (n=6), bruising (n=4); failure in lancet activation (n=4); scarring (n=2); device damaged (n=1); poor adhesive, device fell off arm (n=1) (Tasso personal communication).

Recently, HJF performed an institutional review board (IRB)-approved (PC09_WCG20226038) evaluation of the second-generation Tasso+™ devices entitled "Comparison of collection of venipuncture blood vs. mild vacuum pressure collection devices on studies of plasma, serum, whole blood, and cellular derivatives." This protocol enrolled 10 subjects during April and May 2023 for 2 encounters (2 Tasso+™ second generation devices per encounter) under supervision. The two encounters were 42 days apart. In this study, the Tasso+™/LH collection kits were used with the Tasso+™ devices. Four of ten subjects reported scarring up to 28 days from the first visit, and 1 subject reported bruising after the first visit. Approximately 50% of the collected

samples showed evidence of clotting. A majority of the subjects reported their preference for Tasso blood collection versus venipuncture (HJF personal communication).

1.2 Study Rationale

COVID-19 demonstrated the potential of pandemics to overwhelm local and state medical infrastructures to diagnose and treat patients, while attempting to minimize further transmission risks to the un-infected. Furthermore, the COVID-19 pandemic has impacted the conduct of clinical trials of medical products, leading to challenges in meeting protocol-specified procedures, including adhering to protocol-mandated visits and laboratory/diagnostic testing. Overall, the emergence of DCTs may help improve trial participant engagement, recruitment, enrollment, and retention of a meaningfully diverse clinical population.

Enabling technologies that would enable the collection of blood and other diagnostic samples at the point-of-care by the patient/participant while at a remote location could potentially offer several benefits, eg, improved patient/participant convenience and comfort, early diagnostic sampling (and thereby potentially early diagnosis), greater participant study compliance (especially for pharmacokinetic and biomarker research endpoints), relief of phlebotomy-related bottlenecks while reducing any potential transmission risks.

Advancing technologies that can enable blood collections by the patient or study participant while remaining at a remote location provide a potentially attractive alternative for patients who are not critically ill. These technologies have the potential to minimize transmission-risk and accelerate the timeline for diagnosis and treatment. Furthermore, this would allow for the better channeling of potentially limited medical resources (eg, phlebotomists, HCP) toward managing a pandemic response. In a clinical trials' setting, this may be more attractive to study participants, sparing them the need for frequent clinic visits, and would reduce the overall costs associated with frequent clinic visits.

Enabling such self-collection devices has the potential to take the initial evaluation of a patient closer to the point-of-care, supporting telemedicine strategies and virtual clinical trials. Advancing such innovative technologies requires that device performance and user experience be compared to the current standard of care offered by in-clinic HCPs.

Examples of Tasso device use for SARS-CoV-2 antibody testing have been published in the literature. In one study, the use of Tasso device for capillary blood self-collection was associated with a high success rate (93.4% of participants in unsupervised settings and 94.5% of participants in supervised settings) and an excellent concordance (overall accuracy of 98.9%) for anti-SARS-CoV-2 IgG results when compared to standard venous blood-derived sera (Hendelman et al., 2021). In another study, 70.0% of participants were able to collect an adequate sample for testing using the Tasso device. Among those with an adequate sample, there was a high concordance in results between the Tasso/SST and phlebotomy blood collection methods (Cohen's kappa coefficient = 0.88). Moreover, the

Tasso device receives a high-level (90.0%) of acceptance among all participants (Wixted et al., 2022). To note, the higher failure rate (30.0%) observed by Wixted et al., (2022) compared to the failure rate of 6.6% observed by Hendelman et al., (2021) could be due to an older population (median age and range of 58.0 years [45.0 to 68.0 years] vs 45 years [21 to 73 years]), in which manual dexterity or comorbidities could be more likely to affect use of the device.

The Tasso+™ lancet is an enabling technology that is an FDA 510(k)-cleared Class II medical device that aims to improve upon the traditional venipuncture blood collection experience. This study aims to evaluate the third generation Tasso+™ device with Tasso+™/SST and Tasso+™/EDTA collection kits with respect to device performance and user experience in adult participants who are healthy or in well-compensated health. The Tasso+™/SST collection kit will be used to evaluate serum while the Tasso+™/EDTA collection kit will be used to evaluate whole anticoagulated blood and plasma.

The laboratory results of Tasso+™/SST capillary collection tube will be compared on Day 1 to blood collected using the standard venipuncture by an HCP across an array of laboratory tests being tested by laboratory technicians at a single central laboratory (Table 4).

Establishing correlation coefficients of laboratory results collected by a study participant and compared to standard venipuncture will be an important milestone to rely solely on the patient/study participant to self-collect blood using either device/kit collected and to ship the samples to a designated laboratory. Indeed, in a recent study, even though Tasso/SST serum protein measurements were highly reproducible, self-collection at home with delayed sample processing was associated with significant concentration differences for several analytes compared to supervised, in-clinic collection with rapid processing (Brandsma et al., 2022). These results are to be compared to higher concordance results obtained among other studies focusing on serology: overall accuracy of 98.9% in the study conducted by Hendelman et al., (2021) and Cohen's kappa coefficient of 0.88 in the study conducted by Wixted et al., (2022).

The sample integrity of Tasso+™/SST (ie, adequate volume and absence of moderate or gross hemolysis) and Tasso+™/EDTA (ie, adequate volume, absence of moderate or gross hemolysis, and absence of clotting) capillary collection tubes will be evaluated on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined (Table 4).

Table 4 Sample Testing Table

Method of blood collection		Laboratory Results		Sample Integrity		
		SARS-CoV-2	Chemistry*	Sample Volume	Hemolytic Index	Clotting
Tasso+™ device	EDTA	✓		✓	✓	✓
	SST	✓	✓	✓	✓	
Venipuncture	EDTA	✓				
	SST	✓	✓			

EDTA=ethylenediaminetetraacetic acid; SST=serum separator tube
Footnotes: Chemistry analytes include sodium, potassium, chloride, blood urea nitrogen, creatinine, glucose, phosphate, uric acid, and C-reactive protein.
There will be no complete blood count laboratory analysis using Tasso+™/EDTA capillary collection tube due to potential for red cell lysis and clotting, and insufficient blood volume collection that may preclude accurate results.

The impact of the timing of centrifugation after blood collection with Tasso+™ on blood sample integrity and accuracy will be evaluated on Day 1, as Tasso+™ blood samples of Cohort A participants will be centrifuged after shipping to the Central Laboratory, while Tasso+™ blood samples of Cohort B participants will be centrifuged and aliquoted by the Site prior to being shipped to the Central Laboratory alongside with venipuncture blood samples that will be centrifuged prior to shipping as per standard procedures.

Subsequent Tasso+™ administrations will be conducted remotely by the study participant to further document the device performance and user experience. Participants will receive proctor-support from the Site on Day 29 (and if requested, on Day 57). The results of this study may provide data to ensure the feasibility of decentralized, blood collections, thus supporting telemedicine strategies and virtual clinical trials.

1.3 Benefit/Risk Assessment

Risks to study participants include pain, tenderness, redness, swelling, bruising, and persistent bleeding at the puncture site, as well as dizziness, and fainting, that is also occasionally experienced with venipuncture. There is also a slight risk of infection and scarring.

Additionally, collection of upper respiratory fluid using a nasopharyngeal swab for the SARS-CoV-2 polymerase chain reaction (PCR) test may cause discomfort.

Study participants will self-collect blood using the Tasso+™ following appropriate training/instructions (including remote support from a proctor) to complete the administration successfully while minimizing any potential risks associated with the use of Tasso+™ device. Contact information will be provided to each participant in the event they have concerns or need help while using the Tasso+™ device.

There are no direct benefits to participants in this study. However, information collected from this study may be used to improve remote testing and/or diagnostics and to develop telemedicine, thus benefiting ill patients during future pandemics and study participants enrolled in DCTs.

In conclusion, considering the measures planned to minimize risks to study participants, any potential risks associated with the use of the Tasso+™ device are justified by the anticipated benefits afforded by telemedicine.

2 STUDY OBJECTIVES

2.1 Primary Objective

The primary objective is to assess the Tasso+™ performance (sample integrity, testing accuracy, and reliability).

2.2 Secondary Objectives

The secondary objectives are to evaluate Tasso+™ user experience (safety, tolerability, and usability) and to perform surveillance for SARS-CoV-2 infection.

2.3 Exploratory Objective

To evaluate the impact of prior training on subsequent Tasso+™ administrations.

3 STUDY ENDPOINTS

3.1 Primary Endpoints

The primary endpoints that will be evaluated to assess the Tasso+™ blood collection device performance are as follows:

Sample integrity

- Percentage of overall Tasso+™/SST samples collected that are with adequate volume and without moderate or gross hemolysis on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined
- Percentage of overall Tasso+™/EDTA samples collected that are with adequate volume, without moderate or gross hemolysis, and without clotting on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined

Testing accuracy

- Correlation of SARS-CoV-2 serology between venipuncture and Tasso+™/SST or Tasso+™/EDTA samples on Day 1 for each cohort
- Correlation of each chemistry analyte between venipuncture and Tasso+™/SST samples on Day 1 for each cohort

Reliability

- Percentage of Tasso+™ device failures from Day 1 to Day 57 (see details in Section 6.3.3), defined as:
    - failure in activation of the lancet;
    - lack of any blood collection within 5 minutes;
    - incorrect attachment of the capillary collection tube to the device;
    - damage to the device or the capillary collection tube upon handling;
    - lack of maintained seal between the device and the skin surface of the participant; or
    - incomplete trigger of the button (not fully pressing the button once the Tasso+™ device is sealed to the skin surface).

3.2 Secondary Endpoints

The secondary endpoints that will be evaluated to assess the Tasso+™ user experience and to perform a surveillance study for SARS-CoV-2 infection are:

Safety

- Percentage of eligible participants who experience solicited local AEs including pain, tenderness, redness, swelling, or bruising within 7 days of Tasso+™ administration
- Percentage of eligible participants who experience unsolicited AEs within 28 days of Tasso+™ administration

- Percentage of eligible participants who experience a related Grade 3 AE, a related Grade 4 AE, a related AE leading to discontinuation, or a related SAE within 28 days of Tasso+™ administration

Tolerability

- Percentage of eligible participants who complete last Tasso+™ administration (Day 57)

Usability

- Ease of use as assessed by the participant completing the Tasso questionnaire immediately following administration (on Days 1, 29, and 57) and on Day 85

SARS-CoV-2 infection surveillance

- Percentage of eligible participants with a positive nasopharyngeal swab for SARS-CoV-2 PCR on Day 1
- Percentage of eligible participants seroconverting to SARS-CoV-2 between Days 1 and 57

3.3 Exploratory Endpoint

The exploratory endpoint will evaluate the impact of prior training on subsequent Tasso+™ administrations using descriptive analyses of proctor-supported and proctor-unsupported Tasso+™ administrations on Day 57 using each of the following endpoints:

- Sample integrity
- Reliability
- Safety
- Usability

4 STUDY PLAN

4.1 Overall Study Design and Plan

This is a Phase 1, multicenter, observational study that will evaluate the Tasso+™ device in approximately 200 male or female adult participants in an outpatient setting who are healthy or in well-compensated health at up to 5 US sites.

The Investigator will obtain electronically signed informed consent (eConsent form) from the participant before any study procedures are performed. For further details regarding the informed consent process, see Section 11.3.

Each participant will be followed with a study visit in the Clinic on Day 1, and subsequent decentralized, remote study visits on Days 29, 57, and 85. The total duration of study participation is expected to be 85±3 days.

On Day 1, each participant will be randomized 2:1 to either Cohort A or Cohort B. Tasso+™ blood samples of participants randomized to Cohort A will be shipped to the Central Laboratory where they will be centrifuged and aliquoted. However, Tasso+™ blood samples of participants randomized to Cohort B will be centrifuged and aliquoted at the Site prior to shipping to the Central Laboratory, following the same approach used for venipuncture blood samples.

The decentralized visit on Day 29 (Visit 2) will be remotely supported by a prescheduled proctor during working hours to support the participant's self-administration of the Tasso+™ device. For the decentralized visit on Day 57 (Visit 3), the participant will have the option to request a prescheduled proctor session during working hours to support the participant's self-administration of the Tasso+™ device.

The participant will use an electronic diary (eDiary) to report symptoms for 28 days following each Tasso+™ device administration (Symptom questionnaire) and to report on the usability of the Tasso+™ device (Tasso questionnaire) immediately following each Tasso+™ device administration (on Days 1, 29 and 57) and on Day 85. Contact information will be provided to each participant in the event they have concerns or they need help during working hours while using the Tasso+™ device.

Venous blood collection (phlebotomy) will take place on Day 1; capillary blood collections using Tasso+™ device will take place on Days 1, 29, and 57; usability data will be collected after each use of Tasso+™ device and on Day 85; reliability of the device will be collected after each use of Tasso+™ device (Days 1, 29, and 57).

Each Tasso+™ capillary blood collection will be followed by a 28-day follow-up period during which safety of the Tasso+™ device will be assessed using an eDiary (Symptom questionnaire). Solicited symptoms will be assessed for the first 7 days following each Tasso+™ administration, while unsolicited AEs will be captured for the full 28-day period after each administration.

Each self-collected Tasso+™ blood sample will be assessed for sample integrity by the Central Laboratory. Moreover, on Day 1, the self-collected capillary blood sample will be compared to a venous blood sample collected by an HCP, in order to assess device performance.

Each participant will receive nasopharyngeal swabbing on Day 1 for SARS-CoV-2 PCR testing to identify any baseline SARS-CoV-2 infections. The nasopharyngeal swab will be performed and resulted by the Site. Participants with positive results may remain on study but will be referred to their primary physician for COVID-19 management. During the study, if participants experience any COVID-19 symptoms or if they became COVID-19 positive, they are to be reported to the Investigator via provided Site's phone number. Management of COVID-19 positive participants is detailed in Section 4.4. SARS-CoV-2 antibody testing (Days 1 and 57) will be conducted to serologically identify intervening COVID-19 cases, or if in the absence of intervening symptoms, SARS-CoV-2 infections.

The Study Schematic and Schedule of Assessments are available in Figure 1 and Table 1 respectively.

See Section 7.4 for an overview of instruction for use (IFU) of Tasso+™ device. The detailed IFU will be provided in a separate document.

4.2 Steps to the Process

4.2.1 Training

Training will be provided on Days 1 and 29 and will include detailed IFU and online video training. The detailed IFU will be provided in a separate document, and an overview of IFU is provided in Section 7.4. When administering the Tasso+™ remotely, participants will receive proctor-support from the Site on Day 29 (and as requested, on Day 57) during working hours, the intent being to guide the participant through the process and to help troubleshoot should any difficulties be encountered. Training on Day 57 should be performed only if it is specifically requested due to participant hesitation.

4.2.2 Blood Collection

Once trained, and by following the IFU provided (see Section 7.4), participants will self-administer the Tasso+™ device in the Clinic at the Investigator site (supervised) and subsequently remotely, ie, at home or a suitable remote location (proctor-supported on Day 29 and unsupported on Day 57). Self-collection may be additionally supported on Day 57 using a proctor session, as requested, to guide the participant through the process and help to troubleshoot any difficulties. The SST tube will be preferably collected from the left upper arm and the EDTA tube will be preferably collected from the right upper arm.

As per IFU, participants will have to gently invert the Tasso+™ capillary collection tubes after the full collection process is completed.

4.2.3 Blood Volume and Clotting Analyses

Blood volume and clotting analyses will be assessed before centrifugation. Thus, for Cohort B, on Day 1, these endpoints will be assessed by the Site, while for Cohort A, on Day 1 and for Cohorts A and B combined on Days 29 and 57, these endpoints will be assessed by the Central Laboratory (see Section 6.3).

4.2.4 Centrifugation

Tasso+™ blood samples of participants randomized to Cohort A, collected on Day 1, will be centrifuged upon receipt by the Central Laboratory, as per the real-world use of Tasso+™.

Tasso+™ blood samples of participants randomized to Cohort B, collected on Day 1, will be centrifuged and aliquoted by the Site before shipping, following the same procedure as for venipuncture blood samples.

Tasso+™ blood samples of participants from both Cohorts A and B, collected on Days 29 and 57, will be centrifuged upon receipt by the Central Laboratory, as per the real-world use of Tasso+™.

Thus, for Cohort B, on Day 1, centrifugation and aliquoting will be performed by the Site, while for Cohort A, on Day 1 and for Cohorts A and B combined on Days 29 and 57, centrifugation and aliquoting will be performed by the Central Laboratory.

4.2.5 Shipping

On Day 1, Tasso+™ and venipuncture collection tubes will both be shipped by the Site following this visit.

On Days 29 and 57, blood will be shipped by the participant (remotely proctor-supported and unsupported, respectively).

4.2.6 Hemolysis Analysis

Hemolytic index will be assessed before testing by the Central Laboratory (see Section 6.3).

4.2.7 Testing

Upon receipt, both SST and EDTA samples will be tested by Central Laboratory (see Section 6.3).

4.3 Management of Device Failures

Device failures, as a measure of reliability, will be assessed, as part of evaluating device performance.

Device failures due to deficiencies or malfunctions (see Sections 8.1.6 and 8.1.7) are defined as failure in activation of the lancet, or lack of any blood collection within 5 minutes.

Device failures due to user errors (see Sections 8.1.8) consist of incorrect attachment of the capillary collection tube to the device, damage to the device or the capillary collection tube upon handling, lack of maintained seal between the device and the skin surface of the participant, or incomplete trigger of the button (not fully pressing the button once the Tasso+™ device is sealed to the skin surface) (see Section 6.3.3 for details).

On a case-by-case basis, in the event of collection failure, either related to user or device, as per the protocol-specific laboratory manual, an additional device/kit may be provided to the participant, so that proctor-supported or unsupported capillary blood collection can be performed for a second time, 1-inch away from the previous administration site.

A proctor session may be triggered by the participant (during working hours) in order to claim for help or report any concern related to the unsupported use of Tasso+™ device. Contact information will be provided to each participant in the event they have concerns or they need help while using Tasso+™ device.

In the event of collection failure, the participant should contact the Site for instructions on how the device should be returned to the clinic for evaluation.

4.4 Management of COVID-19 Positive Participant

According to the Center for Disease Control and Prevention (CDC), people with COVID-19 have had a wide range of symptoms reported – ranging from mild symptoms to severe illness. Symptoms may appear 2-14 days after exposure to the virus. Symptoms may include fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea (CDC, 2022).

On screening, any participant who tests positive for SARS-CoV-2 PCR will be permitted to continue study participation. However, the Investigator will assess for the presence of any symptoms of COVID-19 and will refer the participant to their primary physician if the participant is symptomatic.

In the event that a participant seroconverts to SARS-CoV-2 between Day 1 and Day 57, the participant will be assessed as to whether any symptoms of COVID-19 had been experienced during the intervening period. This will distinguish SARS-CoV-2 infection from COVID-19 (see Section 6.3.7). Medical costs associated with COVID-19 will not

be covered by the Sponsor. The site staff will not be expected to treat participants for COVID-19 symptom management.

4.5 End of Study

The end of the study is defined as the date the last participant receives final assessment.

4.5.1 Completion

A participant is considered to have completed the study if he/she has completed all study visits.

4.5.2 Discontinuation

Participants will be discontinued by the investigator if:

- participant is hospitalized due to COVID-19.
- participant develops an illness that would interfere with his/her continued participation in the study.
- participant experiences a related AE leading to study discontinuation.
- participant experiences a related Grade 3 AE, a related Grade 4 AE, or a related SAE that may interfere with the participant's study involvement.
- participant is noncompliant with study procedures, in the opinion of the Investigator.
- participant is lost to follow-up (ie, who misses more than 1 visit or fails to complete the eDiary for more than 7 consecutive days without justification).
- any other reason relating to the participant's safety or integrity of the study data.

Discontinued participants meeting the above criteria will not be replaced. If a participant is discontinued from the study early, the assessments planned for the last follow-up/end of study Visit should be completed at the time of discontinuation.

4.5.3 Withdrawal

Participants can terminate their study participation at any time without prejudice. If participation termination occurs before completing the study, the reason for this decision, if provided, will be recorded in the study notes.

Participants who withdraw from the study will not be replaced.

A participant will be considered withdrawn if consent is withdrawn prior to the completion of the last follow-up/end of study Visit. If a participant withdraws from the study early, the assessments planned for the last follow-up/end of study Visit should be completed at the time of withdrawal.

4.5.4 Study Halting Criteria

Study activities will be halted at any time if medically indicated. Study activities must be stopped, and a review of available safety data will be evaluated if the following occur:

- Malfunction of the device resulting in unexpected severe harm to any participant.

5 STUDY POPULATION

A total of approximately 200 eligible participants will be enrolled at up to 5 clinical sites in the US. Participants must meet all of the inclusion criteria and none of the exclusion criteria to be participating in the study.

5.1 Inclusion Criteria

The following inclusion criteria must be met for a participant to be eligible for participating in the study:

1. Male or female adults (18 years of age or older, inclusive), at the time of informed consent. Participants who are deemed pregnant by urine pregnancy test at Screening remain eligible.

2. Able to understand and willing to provide informed consent and able to comply with the study procedures and restrictions.

3. Participant considered healthy or in well-compensated health according to medical history, concomitant medications, and physical examination (including vital signs).

5.2 Exclusion Criteria

A participant who meets any of the following exclusion criteria will not be eligible for participating in the study:

1. Medical history, or physical examination (including vital signs) findings, that suggest to the Investigator that the participant has undiagnosed or untreated medical condition(s) that could confound the AE evaluation and thereby undermine the study objectives.

2. Any known medical history of infection with HIV (CD4<200 and/or detectable viral load within the prior 3 months), hepatitis B (positive HBsAg), or hepatitis C (positive hepatitis C virus antibody).

3. Chronic illness for which a participant's immune system is suspected by the Investigator to be impaired or altered, such as cancer, autoimmune conditions, and diabetes.

4. Participation in another investigational study within 30 days of time of consent or plans to do so during the course of this study.

5. Large tattoos or skin eruptions overlying either of the deltoid muscles that could confound the monitoring for local reactogenicity following Tasso+™ administrations.

6. Use of systemic immunomodulatory therapy, including oral corticosteroids, within the past 6 months; or planned use of medications or nutritional supplements known to

or which potentially could affect organ function within 30 days prior to screening until end of study.

7. Acute illness within 14 days prior to device use unless it is determined by the Investigator that the illness is mild in severity and unlikely to progress.

8. Of limited legal capacity.

9. Any condition (including suspected alcohol- or drug-related addiction) that precludes adequate understanding, cooperation, and/or compliance with study procedures or any condition that could pose a risk to the participant's safety per Investigator judgment.

5.3 Screen Failures

Subjects who do not meet 1 or more criteria required for eligibility will not be enrolled in the study. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants, to meet the Consolidated Standards of Reporting Trials publishing requirements, and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, eligibility criteria, and any SAE.

Individuals who are reported under screen failures, because of acute illness (exclusion criterion #7), may be rescreened 14 days after recovery of acute illness.

5.4 Premature Withdrawal/Discontinuation from the Study

Participation in the study is strictly voluntary. A participant has the right to withdraw from the study at any time for any reason, without any reprisal.

The Investigator/Sponsor has the right to discontinue a participant from the study for any of the following reasons:

- The participant is hospitalized due to COVID-19.
- The participant develops an illness that would interfere with his/her continued participation in the study.
- The participant experiences a related AE leading to study discontinuation.
- The participant develops a related Grade 3 AE, a related Grade 4 AE or a related SAE that may interfere with the participant's study involvement.
- The participant is noncompliant with study procedures, in the opinion of the Investigator.
- The participant is lost to follow-up (ie, who misses more than 1 visit or fails to complete the eDiary for more than 7 consecutive days without justification).
- The regulatory agency requests withdrawal of the participant.
- Any other reason relating to the participant's safety or integrity of the study data.

If a participant is discontinued from the study, the study monitor/Sponsor will be informed immediately. If there is a medical reason for discontinuation, the participant

will be referred to their primary physician, if warranted, for clinical management. The participant will be requested to inform the Investigator of their clinical progress.

If the participant withdraws consent for disclosure of further information, the Sponsor may retain and continue to use any collected data before such a withdrawal of consent. If a participant withdraws from the study, he/she may request destruction of any samples taken and not tested, and the Investigator must document this in the site study records.

Although a participant is not obliged to give his/her reason(s) for withdrawing prematurely from a study, the Investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the participant's rights.

At the time of premature study discontinuation, the Investigator should make every effort to ensure the participant completes the assessments indicated at the end of study Visit; see Table 1.

Participants who prematurely discontinue from the study cannot subsequently rejoin the study.

For details on the discontinuation of clinical sites or the study as a whole, see Section 15.

6 DESCRIPTION OF STUDY PROCEDURES AND ASSESSMENTS

A detailed schedule of study procedures and assessments is provided in Schedule of Assessments (Table 1).

6.1 Recruitment/Screening Visit

6.1.1 Recruitment

A detailed schedule of study procedures and assessments is provided in Schedule of Assessments (Table 1).

Potentially interested individuals to be recruited by clinical sites for potential study enrollment:

- Presenting for routine diagnostic testing
- Referred by their healthcare provider
- Review of records at the clinical sites
- Recruitment messaging through social media and other printed or electronic advertising (communication materials to be approved by the IRB prior to implementation).

6.1.2 Informed Consent

Each participant will electronically sign an eConsent form before any study-related procedures takes place. This includes sample collection; any sample used for the purpose of the study cannot be obtained before the participant has consented to the study.

The objective of the study will be explained to the participant during their Day 1 Visit (Table 1). After these explanations, the participant has an opportunity to review the eConsent form and ask questions before deciding to participate in the study and before being asked to electronically sign an IRB-approved eConsent form prior to conduct of any study procedures. Then, demographics, medical history, vital signs, physical examination, and eligibility will be assessed, if deemed eligible for the study participation (see Sections 5.1 and 5.2).

6.1.3 Demographics

Demographic data, including year of birth/age, sex, and race, will be recorded in the eCRF.

6.1.4 Medical History

A brief relevant medical history (notably within the past 5 years), including any ongoing illnesses, as well as COVID-19 illness/vaccine history, will be collected from participants to assess whether any concurrent medical condition may impact assessment of COVID-19 symptoms (eg, active, significant pulmonary disease) or pose additional risk for participation in the study. Any ongoing illness/condition will be recorded in the eCRF,

with the start date and stop date (if applicable, with at least a year recorded if no exact date) of the illness/condition.

Any relevant pre-study procedures (notably within the past 5 years) will be recorded in the eCRF as part of the medical history assessment.

6.1.5 Vital Signs

Participants will undergo vital signs assessment, as indicated in the Schedule of Assessments (Table 1).

Heart rate, systolic and diastolic blood pressure, respiratory rate, SpO_2 by pulse oximetry, and body temperature will be measured. Heart rate and blood pressure measurements should be taken in the supine position and preceded by at least 5 minutes of rest.

6.1.6 Physical Examination

Participants will undergo physical examination, as indicated in the Schedule of Assessments (Table 1).

The complete physical examination will include assessments of the standard physical examination items, including general appearance, skin, eyes, ears, nose, throat, head and neck, heart, chest and lungs, abdomen, extremities, lymph nodes, musculoskeletal, neurological, and other body systems, if applicable, for describing the status of the participant's health.

Investigators should pay special attention to clinical signs related to previous serious illnesses. Any new abnormalities or worsening of existing abnormalities should be reported as AEs, as appropriate (see Section 8).

6.1.7 Pregnancy Test

At Screening, female participants will perform a urine pregnancy. Regardless of the test result (positive or negative), the participant will remain eligible for study participation. Thus, the participant will remain eligible in case of positive pregnancy test. However, medical costs associated with the pregnancy will not be covered by the Sponsor, as the risk to participants has been considered non-significant (see Appendix II).

6.1.8 Identification

At the screening, after eConsent form signature, a unique identification number will be assigned to each participant. The participant will be referenced by this ID throughout the study. The study manual of procedures describes the identification assignation in full.

6.2 Study Visits (Days 1, 29, 57, and 85)

The Day 1 Visit will occur at the clinical site and subsequent visits on Study Days 29, 57, and 85 will occur remotely. On Day 1, participants will be provided and trained on an eDiary that will allow them to record their symptoms (Symptom questionnaire) and usability (Tasso user questionnaire). The eDiary entries will be reviewed at each visit and any recorded symptoms will be entered into the electronic data capture (EDC) database.

Participants will complete the user questionnaire (available in eDiary), provided by Tasso, immediately following each Tasso+™ device administration. The user questionnaire consists of questions about their user experience including assessing their willingness to use the Tasso+™ device repeatedly and at what frequency, any pain or discomfort experienced, their preference to venipuncture and finger-sticks, the ease of comprehension of the instructions and training, and the healing of the collection site.

Venous blood will be obtained from participants at the clinical site on Day 1 using syringe or Vacutainers, as described in the Schedule of Assessments (Table 1). Heart rate and blood pressure measurements should be taken in the supine position, preceded by at least 5 minutes of rest. Body temperature will be taken by ear/tympanic/temporal, oral, or forehead method.

Clinician supervised collection of blood using the Tasso+™ device will be performed at Day 1 Visit and collection of blood using the Tasso+™ device will be performed remotely on Day 29 (proctor-supported) and on Day 57 (intended to be unsupported). There will be two collections, one from each arm; left upper arm will be preferably used for serum preparation (Tasso+™/SST capillary collection tube with gold cap, see Table 2) and right upper arm will be preferably used to collect whole blood (Tasso+™/EDTA capillary collection tube with lavender cap, see Table 2). During Visits 2 and 3 (Days 29 and 57), Tasso+™ device will be self-administered by the participant. On Day 29, the self-collection will be supported by a proctor (during working hours). On Day 57, self-collection may be additionally supported by a proctor to guide the participant through the process and help to troubleshoot any difficulties (during working hours). Contact information will be provided to each participant in the event they have concerns or they need help while using Tasso+™ device.

On Day 1, Tasso+™ and venipuncture collection tubes will both be shipped by the Site following this visit.

On Day 29 and 57, blood will be remotely collected and shipped by the participant (proctor-supported and unsupported, respectively).

Training will consist of a detailed IFU and online video training. The detailed IFU will be provided in a separate document, and an overview of IFU is provided in Section 7.4. In addition, when administering the Tasso+™ remotely, participants will receive proctor-support on Day 29 (and as requested, on Day 57), during working hours, the intent being to guide the participant through the process and to help troubleshoot should any difficulties be encountered. While assistance will be available to the participant during

Day 57 Visit, it is of interest to know whether the prior trainings on Tasso+™ administration prove adequate for this subsequent administration.

Nasopharyngeal swabs for qualitative and/or quantitative SARS-CoV-2 PCR will be performed and resulted by the Site. Nasopharyngeal swabs will be collected on Day 1 according to the site's standard operating procedures (SOP) and according to institutional and test kit manufacturer's SOP or instructions and resulted by institutional laboratory. Specimen labels will include protocol number, participant ID number, and date of collection.

6.3 Endpoint Assessments

Endpoint assessments should be completed as specified in Schedule of Assessments (Table 1).

The primary objective of the study, which is the evaluation of Tasso+™ blood collection device performance, will be assessed with regards to sample integrity (see Section 6.3.1), testing accuracy (see Section 6.3.2), and reliability (see Section 6.3.3) of the device.

The secondary objectives of the study, which are the evaluation of user experience and the surveillance for SARS-CoV-2 infection, will be assessed with regards to safety (see Section 6.3.4), tolerability (see Section 6.3.5), and usability (see Section 6.3.6) of the device as well as SARS-CoV-2 infection surveillance (see Section 6.3.7).

6.3.1 Sample Integrity

Sample integrity of the Tasso+™ device, as part of device performance, will be evaluated as the percentages of Tasso+™/SST and Tasso+™/EDTA samples with adequate volume and without moderate or gross hemolysis, and the percentage of Tasso+™/EDTA samples without clotting. These endpoints will be assessed on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined.

Blood collection volumes for Tasso+™ kits are ranging 400 to 600 µL for Tasso+™/SST kits and 250 to 500 µL for Tasso+™/EDTA kits. Adequate whole blood volume is defined as collected volume in accordance with the testing plan, ie, 300 µL. Desired volume is defined as adequate volume, which is doubled, ie, 600 µL, to allow retesting. The volume of blood collected with the Tasso+™ system will be measured in the Central Laboratory.

As defined by Central Laboratory SOP, the absence or presence of hemolysis is defined using the hemolytic index (Table 5). Thus, absence of moderate or gross hemolysis is defined as a hemolytic index <2.00.

Table 5 Impact of Varying Degrees of Hemolysis (Measured by Hemolytic Index) on Validity of Laboratory Results

Degree of Hemolysis	None	Slight	Moderate	Gross
Hemolytic Index	<0.3	≥0.3 and <2.0	≥2.0 and ≤5.0	>5.0
Sodium	No effect	No effect	No effect	All results invalidated
Potassium			Potassium results invalidated	
Chloride			No effect	
Blood urea nitrogen			No effect	
Creatinine			No effect	
Glucose			No effect	
Phosphate			Phosphate results invalidated	
Uric acid			No effect	
C-reactive protein			No effect	
SARS-CoV-2 serology			No effect	

Presence or absence of clotting in the Tasso+™/EDTA samples will be assessed by Central Laboratory on samples collected on Days 1, 29, and 57.

6.3.2 Testing Accuracy

Testing accuracy of the Tasso+™ device, as part of device performance, will be evaluated as (i) the correlation of SARS-CoV-2 serology between venipuncture and either Tasso+™/SST or Tasso+™/EDTA samples collected on Day 1; and (ii) the correlation of each chemistry analyte between venipuncture and Tasso+™/SST samples collected on Day 1. This endpoint will only be assessed on Day 1 for each cohort separately.

Seroconversion will be evaluated using IgG Nucleocapsid assay. A total serum (SST) or plasma (EDTA) volume of 175 µL will be necessary to cover potential retesting, if needed. Any participant who is positive for IgG Nucleocapsid assay for either matrix (SST or EDTA), will be considered SARS-CoV-2 positive.

The following chemistry analytes will be assessed for correlation between the two collection approaches (venipuncture and Tasso+™/SST) on Day 1: sodium, potassium, chloride, blood urea nitrogen, creatinine, glucose, phosphate, uric acid, and C-reactive protein.

Noteworthy, in case of long duration between sample collection and testing, there may be risks associated with inaccurate sodium, potassium, and glucose values.

If a sodium, potassium, or glucose level is determined by the PI to be possibly clinically significant, a venipuncture repeat of the test should be performed at the Investigator site for safety reasons. Testing will be performed by the Investigator site and will not be sent to the Central laboratory.

6.3.3 Reliability

Reliability of the Tasso+™ device, as part of device performance, will be measured as the percentage of device failures (failures that either occur due to inherent faulty mechanism of the device or due to user error) from Day 1 to Day 57. This endpoint will be assessed by the participant through completion of the Tasso user questionnaire (available in eDiary) immediately following each Tasso+™ administration.

A device failure due to a faulty mechanism consists of either: (i) failure in activation of the lancet; or (ii) lack of any blood collection within 5 minutes (see Section 7.4).

A device failure due to user error consists of either: (i) incorrect attachment of the capillary collection tube to the device; (ii) damage to the device or the capillary collection tube upon handling; (iii) lack of maintained seal between the device and the skin surface of the participant; or (iv) incomplete trigger of the button (not fully pressing the button once the Tasso+™ device is sealed to the skin surface) (see Section 7.4).

- An unscheduled kit may be used by the participant to re-attempt the administration after reporting the issue to the study staff, following instruction of the protocol-specific laboratory manual.

6.3.4 Safety

Safety of the Tasso+™ device, as part of user experience, will be evaluated as the percentages of eligible participants who: (i) experience solicited local AEs including pain, tenderness, redness, swelling, or bruising within 7 days of Tasso+™ administration; (ii) experience unsolicited AEs within 28 days of Tasso+™ administration; (iii) experience a related Grade 3 AE, a related Grade 4 AE, a related AE leading to study discontinuation, or a related SAE within 28 days of Tasso+™ administration. This endpoint will be assessed throughout the conduct of the study.

Severity and causality definitions are provided in Section 8.2.

6.3.5 Tolerability

Tolerability of the Tasso+™ device, as part of user experience, will be evaluated as the percentage of eligible participants who complete last Tasso+™ administration (Day 57).

6.3.6 Usability

Usability of the Tasso+™ device, as part of user experience, will be assessed using a Tasso questionnaire filled in the eDiary by participants immediately following each

Tasso+™ administration (on Days 1, 29, and 57) and on Day 85. The questionnaire includes questions about user experience, by assessing willingness to use Tasso+™ device again, the pain and discomfort experienced, the preference, the understanding of instructions, and the healing of the collection site hit.

6.3.7 SARS-CoV-2 Infection Surveillance

SARS-CoV-2 infection surveillance will be performed by assessing the percentages of eligible participants with: (i) a positive nasopharyngeal swab for SARS-CoV-2 PCR on Day 1 and (ii) seroconverting to SARS-CoV-2 between Days 1 and 57.

6.4 Safety Assessments

6.4.1 Adverse Events

AEs will be followed, recorded, and reported in line with the procedures described in Section 8.

6.4.2 Pregnancy

Urine pregnancy tests will be performed for participants of childbearing potential on Day 1 as per Schedule of Assessment (Table 1). Regardless of the test result (positive or negative), the participant will remain eligible for study participation. The Investigator will record pregnancy information on the appropriate form and submit it to the Principal Investigator (PI) within 24 hours of the Day 1 Visit. Medical costs associated with the pregnancy follow-up will not be covered by the Sponsor, as the risk to participants has been considered non-significant (see Appendix II).

6.4.2.1 Pregnant Trial Participant (Incidental Pregnancy)

If a participant becomes pregnant, the participant will not be discontinued from the study. The Investigator will record pregnancy information on the appropriate form and submit it to the PI within 24 hours of learning of the participant's pregnancy. Medical costs associated with the pregnancy follow-up will not be covered by the Sponsor, as the risk to participants has been considered non-significant (see Appendix II).

6.4.2.2 Pregnant Partner of a Trial Participant

In the event that the female partner of a male participant becomes pregnant, inclusion of the female partner into the study for safety assessment is not relevant for this Class II medical device, as the risk to participants has been considered non-significant (see Appendix II). Medical costs associated with the pregnancy will not be covered by the Sponsor.

6.4.3 Breastfeeding

Safety assessment of breastfed children is not relevant for this Class II medical device as the risk to participants has been considered non-significant (see Appendix II).

6.5 Sample Collection Storage

The remnants of biological samples from clinical trial participants will be stored by the Central Laboratory, for the duration of the study, in case any retesting is required. After completion of all protocol-specified testing (ie, after database lock), Central Laboratory will not maintain the biological samples any further.

7 INTERVENTIONS

7.1 Investigational Medical Device

Tasso kits which contain Investigational Medical Device will be shipped to the Sites by Central Laboratory in ICON kit boxes labeled “Exclusively for clinical trial”; no components in ICON kit boxes are investigational.

7.1.1 Description of Investigational Medical Device

Tasso+™ device is a sterile, disposable, integrated capillary blood collection device, including a lancet assembly and a detachable capillary collection tube for the collection of blood by a user or caregiver in remote settings. The device is designed to collect within 5 minutes up to 600 µL capillary blood. The Tasso+™ device is comprised of the collection unit (called Tasso Button) and a capillary collection tube that can be supplied in several different configurations allowing the transportation of the blood. The Tasso+™ device lancet is classified as an FDA 510(k)-cleared Class II medical device in the US. The Tasso+™ device is designed to safely and reliably collect blood in clinical settings, without the need of a highly trained phlebotomist, while minimizing pain to the participant. Total volume of capillary blood collected by Tasso+™ per application will not exceed 1 mL. Participants will have a Tasso+™ device with Tasso+™ kits which either include SST or EDTA capillary collection tube, to be placed on each upper arm at each visit. Shaving of the upper arm area to remove excess body hair may be required.

7.1.2 Preparation, Handling, and Storage

The Investigator (or designee) is responsible for the safe and proper storage of the medical device at the site. The medical device will be stored under controlled conditions according to the storage requirements described on the label(s), ie, 18 to 28ºC (64.4 to 82.4ºF). Tasso+™ kits will be stored under controlled conditions according to the storage requirements described on the label(s), ie, 18 to 25°C (64.4 to 77ºF). The shelf lives of the Tasso+™ devices and Tasso+™ kits are of 12 months. The Investigator (or designee) will instruct the participants to store the medical device and kits in accordance with the instructions on the label(s).

7.1.3 Sterilization

The Tasso+™ kits are sterile. The Tasso+™ device is rendered sterile by e-beam irradiation in accordance with ISO 11137-1, 11137-2, 11737-1, and 11737-2 Sterilization of Healthcare Products. The Tasso+™ device was validated for a minimum sterility assurance level of 10^{-6} following VDmax25 kGy test methods after being built per processes intended for the final configuration of the device. The Tasso+™ device sterilization process is controlled through internal work instructions and checklists.

7.1.4 Packaging, Labelling, and Shipment

The medical device will be packaged and labelled in accordance with all applicable regulatory requirements and Good Manufacturing Practice guidelines.

The Tasso+™ is provided sterile and is packaged in an industry standard polymer tray and Tyvek cover as a primary sterile barrier. All system components are packaged in appropriately constrained packaging including corrugated boxes and labelling.

Shipping is performed in accordance with Tasso SOP for the control and handling of product. Records are kept providing lot traceability for each site and each product.

7.2 Blinding

This is an open-label study. Participants, HCPs, and laboratory technicians will not be blinded to the study intervention.

7.3 Method of Assigning Process

Each participant will have a unique subject screening number obtained from the interactive voice response system (IVRS). Once the participant is deemed eligible, the participant will be assigned a randomization number.

Randomization will be performed via a centralized IVRS. On Day 1, eligible participants will be assigned to either Cohort A or Cohort B in a 2:1 ratio. Each participant will receive a unique randomization number when he/she is assigned treatment. Participants will be allocated to treatment according to the randomization code.

7.4 Instruction for Use

The section below provides an overview of the IFU. The detailed IFU will be provided in a separate document. Instructional video is available on Tasso Inc. website (http://www.tassoinc.com/tassoplus-video). The use of Tasso+™ kit is not intended for use in diagnostic procedures.

The Tasso+™ kit includes the sterile, disposable Tasso+™ blood lancing device, and the supplies necessary to administer the device.

When collecting a sample, the device will be held onto the skin by a mild adhesive. With a press of the button, a sterile lancet will puncture the skin, simultaneously creating a slight vacuum that will help capillary blood flow under gravity into a compatible tube. After a predefined time period, or when the tube is full, the device will be peeled off the skin. The tube will be removed and capped for shipment. The lancet is single use and automatically retracts into the device in a safe position after use.

Preparation steps notably include set-up of the participant, identification of the collection sites, insertion of applicable tube (SST or EDTA) into the device, and warming and cleaning of the collection site.

Collection step notably includes sticking of the device to collection site, activation of the lancet, filling of the tube, removal of the device, closure of the tubes, and inversion of the tubes.

Shipping and final steps notably include writing of participant's ID number on tube, placing of tube in return bag, recording of the time and date of collection, packaging and shipping of tubes to the Central Laboratory, and discarding of leftover material (excepting Tasso+™).

7.5 Precautions and/or Lifestyle Considerations

There are no lifestyle considerations (such as dietary or physical activity restrictions) for this study beyond those listed in the inclusion/exclusion criteria (Section 5). The Tasso+™ devices require a hair-free surface which may need the upper arm area to be shaved.

Tasso+™ device and kits are not intended for more than one use. They should not be used on more than one participant. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple participants are being tested.

For this Study, precautions for use are as follow:

- For use only on a single participant. Discard the entire device after use.
- Do not use after expiration date.
- Single use only.
- Keep out of reach of children.
- Minor bruising or residual marks may occur at the sample collection site.
- Do not resterilize.
- For external use only.
- Use while seated as fainting may occur with any blood sampling procedure.
- Refer to manufacturer's instructions for individual components.
- Do not use if tray has been opened or damaged.

7.6 Prior Medication and Procedures

Prior medication and procedures will be assessed at each visit as per Schedule of Assessment (Table 1).

7.7 Concomitant Medication and Procedures

Concomitant medication and procedures will be assessed at each visit as per Schedule of Assessment (Table 1).

7.8 Accountability

The medical device must not be used for any purpose other than that defined in this protocol. All supplies of the medical device will be accounted for in accordance with Good Clinical Practice (GCP).

The Investigator (or designee) will provide the medical device only to the identified participants in this study, according to the procedures described in this study protocol.

After the end of the study, all unused medical devices should be destroyed at the clinical site or returned to the manufacturing company for destruction. In either instance, complete documentation will be returned to the manufacturing company.

8 ADVERSE EVENTS

8.1 Definitions

8.1.1 Adverse Events

An AE is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in clinical study participants, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated. An AE therefore includes events related to the investigational medical device and procedures involved.

8.1.2 Adverse Device Effects

An adverse device effect (ADE) is any AE related to the use of an investigational medical device. ADE includes AEs resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. ADE also includes events resulting from user error (see Section 8.1.8) or intentional misuse of investigational medical device.

8.1.3 Serious Adverse Events

An SAE is any event that meets any of the following criteria:

- Results in death.
- Severe deterioration in the health of the participant by one or more of the following: (i) a life-threatening illness or injury; (ii) a permanent impairment of a body structure or function including chronic diseases; (iii) in-patient or prolonged hospitalization; (iv) medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or function; (v) fetal distress, fetal death, congenital abnormality or birth defect including physical or mental impairment.

- The event will be considered an SAE when, based upon appropriate medical and scientific judgment, the event may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. SAEs include all serious events independent of whether they have a suspected causal relationship to the device or not.

8.1.3.1 Life-Threatening AE

An AE is life-threatening if the participant was at immediate risk of death from the event as it occurred; ie, it does not include a reaction that, if it had occurred in a more severe form, might have caused death. It does not include an AE or suspected ADE that, had it occurred in a more severe form, might have caused death.

8.1.3.2 AE Requiring Hospitalization

AEs requiring hospitalization should be considered SAEs. Hospitalization for elective surgery, or for procedures planned prior to the participant providing informed consent, or routine clinical procedures that are not the result of an AE (eg, elective surgery for a pre-existing condition that has not worsened) need not be considered AEs or SAEs. If anything untoward is reported during the procedure, that occurrence must be reported as an AE, either 'serious' or 'nonserious' according to the usual criteria.

In general, hospitalization signifies that the participant has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or outpatient setting. When in doubt as to whether hospitalization occurred or was necessary, the AE should be considered serious.

8.1.3.3 Disability/Incapacity

An AE/ADE is incapacitating or disabling if the experience results in a substantial and/or permanent disruption of the participant's ability to carry out normal life functions.

8.1.4 Serious Adverse Device Effects

A serious adverse device effect (SADE) is defined as any ADE that has resulted in any of the consequences characteristic of an SAE (see Section 8.1.3).

8.1.5 Unanticipated Serious Adverse Device Effects

An unanticipated serious adverse device effect (USADE) is defined as any SADE which by its nature, incidence, severity, or outcome has not been identified in the current risk assessment.

8.1.6 Device Deficiencies

Device deficiency is defined as inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. Device deficiencies include malfunctions (see Section 8.1.7), use errors (see Section 8.1.8), and inadequate labelling.

Device deficiencies that did not lead to an AE but could have led to an SADE if (i) either suitable action had not been taken, (ii) intervention had not been made, or (iii) circumstances had been less fortunate; shall be reported to the Sponsor, the IRB/IEC, and the regulatory authorities.

Device incidents/deficiencies will be reported by clinical sites by completing a device incident/deficiency form and providing it to the CRO's safety team.

8.1.7 Malfunctions

Failure of an investigational medical device to perform in accordance with its intended purpose when used in accordance with the IFU or protocol, or investigator brochure (IB).

8.1.8 User Errors

User error is defined as any action or any lack of action that results in a different medical device response than intended by the manufacturer or expected by the user. User error includes slips, lapses and mistakes. An unexpected physiological response of the participant does not itself constitute a user error.

8.2 Assessment of Adverse Events

8.2.1 Severity

AE/ADE severity will be graded according to the following definitions:

- Mild (Grade 1): events require minimal or no treatment and do not interfere with the participant's daily activities
- Moderate (Grade 2): events result in a low level of inconvenience. Moderate events may cause some interference with functioning
- Severe (Grade 3): events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually incapacitating
- Life-threatening (Grade 4): events have life-threatening consequences; urgent intervention indicated

8.2.2 Causality

Investigators are required to systematically assess the causal relationship between the AEs/SAEs and the exposure to the device.

8.2.3 Expectedness

An unexpected (or unanticipated) event is defined as any event which by its nature, incidence, severity, or outcome has not been identified in the current risk assessment.

8.3 Documenting and Reporting Adverse Events

Reporting of AEs will begin when the participant has provided informed consent and will continue up to the end of study Visit. All AEs will be monitored and recorded in the eCRF throughout the described reporting period.

Occurrence of AEs may be volunteered spontaneously by the participant; discovered as a result of general, nonleading verbal questioning by the study staff; or determined by physical examination or other safety assessments.

For all AEs, the Investigator must pursue and obtain adequate information (a description of the event, severity, date of occurrence, duration, and any action, eg, treatment/follow-up tests). The outcome of the event should be provided along with the Investigator's assessment of the relationship to the device. The Investigator must also assess whether the event meets the criteria for classification as an SAE.

It is the Investigator's responsibility to review all documentation (eg, hospital notes, laboratory reports, and diagnostic reports) related to an AE. Wherever possible, the Investigator's diagnosis, not the individual signs and symptoms, will be documented as the AE.

Investigators are not obligated to actively seek AEs or SAEs after the participant's conclusion of study participation. However, if the Investigator learns of any SAE, including death, at any time after a participant has been discharged from the study, and he/she considers the event to be reasonably related to the device or study participation, the Investigator must promptly notify the Sponsor.

Participants will be provided with a Symptom questionnaire (available in eDiary) for recording unsolicited AEs and any concomitant medications used during the study. The participants will be given access to the eDiary on Day 1 and will be asked to record information in the eDiary for the duration of their participation in the study (daily notifications will be sent to the participant). The diaries will not be considered as source documents. Diary data will be transcribed by site personnel to source documents and then from that document, they will be entered into the EDC database and reviewed by the study monitor.

For Grade 3 or Grade 4 AE considered related to device, and AE considered related to device leading to study discontinuation, the Investigator must immediately (no later than 24 hours after becoming aware of the event) inform the Sponsor (or designee) of the AE utilizing the safety report form.

8.4 Reporting of Serious Adverse Events

For SAEs with an onset inside the reporting period, SAEs considered related to device that occur after this reporting period, and device deficiencies that did not lead to an AE but could have led to an SADE, the Investigator must immediately (no later than 24 hours after becoming aware of the event) inform the Sponsor (or designee) of the SAE utilizing the safety report form (refer to the SAE contact information at the beginning of this protocol).

The Investigator is obliged to respond to any request for follow-up information (eg, additional information, event outcome, final evaluation, or other records where needed) or to any question the Sponsor (or designee) may have concerning the SAE within the same timelines as those noted above for initial reports. This is necessary to ensure prompt assessment of the event by the Sponsor (or designee) and, as applicable, to allow the Sponsor to meet strict regulatory timelines associated with expedited reporting obligations for events of this nature.

8.5 Adverse Event and Serious Adverse Event Follow-Up

During the study (and after the end of study Visit), all AEs and SAEs should be followed proactively by the Investigator until the event resolves or the condition stabilizes to a level acceptable to the Investigator, until the event is otherwise explained, or until the participant is lost to follow-up. At the time the study participation ends, all ongoing AEs and SAEs should be evaluated for resolution. New or updated information will be recorded in the originally completed eCRF and the Investigator will submit any updated SAE information to the Sponsor within 24 hours of receipt of the information.

8.6 Safety Reporting Oversight

In accordance with International Council for Harmonisation guidelines on Good Clinical Practice (ICH GCP), the Sponsor (or designee) will inform Investigators of "findings that could affect adversely the safety of participants, impact the conduct of the trial, or alter the IEC/IRB's approval/favorable opinion to continue the trial."

The Sponsor has a legal responsibility to notify both the local regulatory authority and other regulatory agencies about the safety of a medical device under clinical investigation. The Sponsor will comply with country-specific regulatory requirements relating to safety reporting to the regulatory authority, IRB/IEC, and Investigators. To support compliance with these requirements, the Investigator must provide requested information in a timely manner.

An Investigator who receives an Investigator safety report describing SAEs or other specific safety information (eg, summary or listing of SAEs) from the Sponsor will file it along with the IB and will notify the IRB/IEC, if appropriate, according to local requirements.

9 STATISTICS

9.1 General Procedures

All personnel involved with the analysis of the study will be unblinded. Analyses will be performed using SAS 9.4 ® (or higher).

The statistical analysis plan (SAP) will be approved prior to the first participant being enrolled. The SAP will provide a detailed description of the statistical methods and expand on the details provided in the protocol.

Descriptive statistics (number of observations, mean, SD, median, minimum, and maximum) will be provided for continuous variables, and counts and percentages will be presented for categorical variables.

9.2 Analysis Sets

The enrolled analysis set will include all participants who provide informed consent. This analysis set will be used to report disposition and screening failures.

The full analysis set (FAS) will include all participants who administered Tasso^{+}™ either in a site-supervised, proctor-supported, or unsupported setting. This analysis set will be the primary set used for analyses/summaries of the primary endpoint, as well as for secondary endpoint of seroconversion.

The per protocol analysis set (PPS) will include all participants in the FAS and who successfully completed all administrations of Tasso^{+}™. This analysis set will be used for sensitivity analyses.

The safety analysis set (SAS) will include all participants who administered the medical device either in a site-supervised, proctor-supported, or unsupported setting. This analysis set will be used for summaries of safety data.

9.3 Sample Size

Sample size was not calculated on a formal statistical basis; however, Sponsor estimates that the sample size will be sufficient to sample the diversity of user experience regarding the unsupported use of Tasso^{+}™ for capillary blood collection.

Each participant will be randomized to either Cohort A or Cohort B in a 2:1 ratio. Thus, it is planned to randomize approximately 133 participants into Cohort A and approximately 67 participants into Cohort B.

9.4 Statistical Methods

9.4.1 Primary Endpoints

9.4.1.1 Sample Integrity

Descriptive statistics will be presented for the FAS and PPS to summarize the proportion of Tasso+™/SST and Tasso+™/EDTA samples collected on Day 1 for each cohort and on each of Days 29 and 57 for Cohorts A and B combined with the following attributes:

- Adequate volume, defined as 300 µL (desired volume defined as 600 µL)
- Without moderate or gross hemolysis, as defined by Central Laboratory SOP (see Table 5 in Section 6.3.1)
- Without clotting, as assessed by the Central Laboratory

9.4.1.2 Testing Accuracy

Pearson's correlation coefficient will be computed to quantify the strength of the direction of the linear relationship between the venipuncture collection and the Tasso+™ collection at Day 1 for each cohort for SARS-CoV-2 serology and each chemistry analyte. This analysis will be presented for both the FAS and PPS.

9.4.1.3 Reliability

- For each participant, the number of failures will be calculated by summing the instances where the device or the collection process has failed as follows:
  - (i) failure in activation of the lancet
  - (ii) lack of any blood collection within 5 minutes
  - (iii) incorrect attachment of the capillary collection tube to the device
  - (iv) damage to the device or the capillary collection tube upon handling
  - (v) lack of maintained seal between the device and the skin surface of the participant
  - (vi) incomplete trigger of the button (not fully pressing the button once the Tasso+™ device is sealed to the skin surface)

- The total number of device usage instances will also be recorded.

- The percentage of failures will be calculated as:

- $$\text{Percentage of failures} = \frac{\text{Number of Instances with Failures}}{\text{Total Number of Device Usage Instances}} \times 100\%$$

- Counts and percentages will be presented for participants in the FAS and PPS.

9.4.2 Secondary Endpoints

9.4.2.1 Safety

Counts and percentages will be presented for participants in the FAS who experience:

- Solicited local AEs (including pain, tenderness, redness, swelling, or bruising)

- Unsolicited AEs
- A related Grade 3 AE
- A related Grade 4 AE
- A related AE leading to discontinuation
- A related SAE

9.4.2.2 Tolerability

The counts and percentages of participants in the FAS who complete the Day 57 Visit will be summarized.

9.4.2.3 Usability

Descriptive statistics will be presented for participants in the FAS for each aspect of the usability questionnaire on Days 1, 29, 57, and 85.

9.4.2.4 SARS-CoV-2 Infection Surveillance

Counts and percentages will be presented for participants in the FAS for:

- Participants with a positive nasopharyngeal swab for SARS-CoV-2 PCR on Day 1
- Participants seroconverting to SARS-CoV-2 between Days 1 and 57

9.4.3 Exploratory Endpoint

Descriptive statistics will be presented for participants who requested proctor support on Day 57 Visit and for participants who completed the Day 57 Visit without using the proctor support, for the following primary and secondary endpoints:

- Sample integrity
- Reliability
- Safety
- Usability

9.4.4 Analysis of Safety

The SAS will be used for the analysis of safety data.

AEs will be coded with MedDRA. AEs are defined as events with an onset date on or after the date of first administration of the medical device and before the date of last administration of the medical device (Visit 3, Day 57±3) +28 days, which corresponds to the Visit 4 (Day 85±3). TEAEs will be presented by system organ class and preferred term in frequency tables. Participants with multiple AEs will be counted only once within each preferred term and system organ class.

Laboratory data (sodium, potassium, chloride, blood urea nitrogen, creatinine, glucose, phosphate, uric acid, and C-reactive protein) will be converted to Système International units for reporting and processing purposes. Absolute values will be presented descriptively. Laboratory data outside study-specific reference ranges will be listed.

9.4.5 Demographic and Baseline Characteristics

Demographic characteristics (including age, sex, ethnicity, and race) and baseline characteristics (including height, weight, BMI, supine systolic and diastolic blood pressure, pulse, body temperature, and respiratory rate) will be presented descriptively.

Prior and concomitant medications will be listed.

Past medical history will be listed.

9.4.6 Subgroup Analyses

There are no subgroups within this study.

9.4.7 Handling of Missing Values

Missing data will not be imputed.

9.5 Interim Analysis

There is no interim analysis for this study.

10 RECORDS MANAGEMENT

All clinical study information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification. This principle applies to all records referenced in this protocol, irrespective of the type of media used.

10.1 Source Documentation

Source documents contain the results of original observations and activities of a clinical investigation. They are the original records in which raw data are first recorded. Source documents include, but are not limited to, medical records (progress notes), ECG and computer printouts, screening logs, completed scales, quality of life questionnaires, and recorded data from automated instruments.

The Investigator/site personnel should maintain adequate and accurate source documents and study records that include all pertinent observations on each of the site's study participants. Source data should be attributable, legible, contemporaneous, original, accurate, and complete. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary (eg, via an audit trail).

All source documents from this study are to be maintained by the Investigator and made available for inspection by authorized persons. The Investigator will provide direct access to source documents/data for study-related monitoring, audits, IRB/IEC review, and regulatory inspections. The Sponsor should verify that each participant has consented to direct access to his/her original medical records (progress notes) for study-related monitoring, audits, IRB/IEC review, and regulatory inspections.

10.2 Case Report Form Completion and Data Management

An eCRF will be used to store and transmit participant information. The file structure and format for the eCRF will be provided by the Sponsor or its representative and should be handled in accordance with the instructions provided.

The eCRF must be reviewed and electronically signed and dated by the Investigator. The Investigator is responsible for verifying that the data entries are accurate and correct by signing the eCRF.

Access to the eCRF will be strictly password protected and limited to personnel directly participating in the study. Data should be entered into the eCRF completely by authorized site personnel (eg, Investigators and the study coordinator). The eCRF must be completed as soon as possible after any participant evaluation or communication. If data are to be changed due to erroneous input or other reason, an electronic audit trail will track the changes. The eCRF and computers that store them must be accessible to study monitors and other regulatory auditors. Changes to the eCRF will be electronically tracked.

Data will be entered/loaded into a validated electronic database using a clinical data management system. Computerized data cleaning checks will be used in addition to manual review to check for discrepancies and to ensure consistency of the data.

During each study visit, a physician participating in the study will maintain progress notes in the participant's medical records to document all significant observations. At a minimum, these notes are to contain:

- The date of the visit and the corresponding day or visit in the study schedule
- General condition and status remarks by the participant, including any significant medical findings. The severity, frequency, duration, and resolution of any reported AE, and the Investigator's assessment as to whether or not the reported AE is related to the device
- Changes (including dosages) in concomitant medications/therapies (including medical foods) or procedures
- A general reference to the procedures completed
- The signature or initials of all physicians making an entry in the medical record (progress notes)

In addition, any contact with the participant via telephone or other means that provides significant clinical information is to also be documented in the medical record (progress notes), as described above.

Information from the medical records (progress notes) and other source documents is to be promptly entered into the appropriate section of the eCRF.

Changes to information in the medical record (progress notes) and other source documents are to be initialed and dated on the day the change is made by the Investigator (or designee). If the reason for the change is not apparent, a brief explanation for the change is to be written adjacent to the change. Changes to the eCRF will be electronically tracked.

The ICON data management department will write a data management plan, which will be finalized prior to performing any data validation.

10.3 Study Files and Record Retention

All data derived from the study will remain the property of the Sponsor. The Sponsor assumes accountability for actions delegated to other individuals, eg, the CRO.

Records must be retained in accordance with the current ICH GCP Guidelines. All essential study documents, including records of participants, source documents, eCRFs, and the medical device inventory, must be kept on file.

Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region, or until at least 2 years have elapsed since the formal discontinuation of the clinical development of Tasso+™. However, essential documents may be retained for a longer period if required by the applicable regulatory requirements or by agreement with the Sponsor. The Sponsor is responsible for informing the Investigator when these documents need no longer be retained.

The Investigator is not to dispose of any records relevant to this study without written permission from the Sponsor and is to provide the Sponsor the opportunity to collect such records. The Investigator shall take responsibility for maintaining adequate and accurate hard copy source documents of all observations and data generated during this study. Such documentation is subject to inspection by the Sponsor, its representatives, and regulatory authorities.

If an Investigator moves, withdraws from a study, or retires, the responsibility for maintaining the records may be transferred to another person who will accept responsibility. Notice of transfer must be made to and agreed by the Sponsor.

11 ETHICS AND RESPONSIBILITIES

11.1 Good Clinical Practice

This study will be conducted in accordance with the Note for Guidance on ICH GCP Harmonised Tripartite Guideline E6 (R1)/Integrated Addendum E6 (R2); US FDA CFR (Title 21 Parts 50, 56, 312); the general guidelines indicated in the Declaration of Helsinki; and all applicable regulatory requirements.

11.2 Institutional Review Board/Independent Ethics Committee

Before initiating a study, the Investigator/institution must have written and dated approval/favorable opinion from the IRBs/IECs for the study protocol/amendment(s), eConsent form, any eConsent form updates, participant recruitment procedures (eg, advertisements), any written information to be provided to participants, and a statement from the IRBs/IECs that such written information comply with GCP requirements (if applicable). A current copy of the IB should be included as part of the written application to the IRBs/IECs.

The IRB/IEC approval(s) must identify the protocol version as well as the documents reviewed. Any amendments to the protocol will require IRB/IEC approval before the implementation of the changes made to the study, except for changes necessary to eliminate an immediate hazard to the study participants.

The Investigator will be responsible for the following:

- Providing written summaries of the status of the study to the IRBs/IECs annually or more frequently in accordance with the requirements, policies, and procedures established by the IRBs/IECs

- Notifying the IRBs/IECs of SAEs or other significant safety findings, including ADEs that are both serious and unexpected, as required by IRB/IEC procedures

- Providing oversight of the conduct of the study at the site and adherence to the requirements of all applicable regulations

- Reporting requests for deviations and reports of deviations if the deviation affects participant's rights, safety, and well-being, or the scientific integrity of the clinical investigation

- Deviations from the protocol to protect the rights, safety and well-being of study participant or to eliminate immediate hazards to study participant, under emergency circumstance, may proceed without prior approval of the Sponsor and the IRB/IEC. In such a case, the Investigator will be responsible for promptly documenting and reporting deviations.

11.3 Informed Consent

In obtaining and documenting informed consent, the Investigator should comply with the applicable regulatory requirement(s) and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the study, the Investigator must have the written and dated approval/favorable opinion from the IRBs/IECs of the eConsent form (including updates) and any other written information to be provided to participants.

- The Investigator or his/her representative will explain the purpose and nature of the study as well as possible benefits, risks, and adverse effects to the participant or his/her legally acceptable representative and answer all questions regarding the study.

- Participants must be informed that their participation is voluntary, and consent can be withdrawn at any point. Participants should be informed of possible treatment alternatives, including the follow-up measures if their participation in the study is discontinued.

- Participants or their legally acceptable representative will be required to electronically sign a statement of informed consent that meets the requirements of US FDA CFR Title 21 Part 50, local regulations, ICH guidelines, Health Insurance Portability and Accountability Act requirements in the US, and the IRB/IEC or clinical site.

- Prior to a participant's enrollment in the study, the eConsent form should be signed and personally dated by the participant or by the participant's legally acceptable representative, and by the person who conducted the informed consent discussion.

- The medical record must include a statement that informed consent was obtained before the participant was enrolled in the study and the date the consent was obtained.

- A copy of the eConsent form and any other information must be provided to the participant or the participant's legally acceptable representative.

- If the eConsent form is revised, the revised form must have received the IRB/IEC's approval/favorable opinion in advance of its use. Participants must be informed of the changes to the eConsent form and must reconsent to the most current version during their participation in the study. The participant or the participant's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the participant's willingness to continue participation in the study. The communication of this information should be documented.

Participants who are rescreened are required to electronically sign a new eConsent form.

11.4 Recruitment Strategy

Potential participants at the clinical sites will be identified and approached for recruitment as described in Section 6.1.1.

11.5 Data Monitoring Committee

Given that the Tasso+™ device is an FDA cleared device and has been deemed to be associated with minimal risk, there are no plans to convene a data monitoring committee for this study.

11.6 Financing and Insurance

11.6.1 Contractual and Financial Details

The Investigator (and/or, as appropriate, the hospital administrative representative) and the CRO will sign a clinical study agreement prior to the start of the study, outlining overall responsibilities in relation to the study. The Sponsor will review the clinical study agreement. The contract should describe whether costs for pharmacy, laboratory, and other protocol-required services are being paid directly or indirectly.

11.6.2 Insurance, Indemnity, and Compensation

Participants will receive compensation for each study visit. Specifics of compensation are described in the eConsent form and approved by the IRB.

11.6.3 Financial Disclosure

Investigators and sub-Investigators will provide the Sponsor with sufficient, accurate financial information as requested, to allow the Sponsor to submit complete and accurate financial certification or disclosure statements to the appropriate regulatory authorities.

12 AUDITING AND MONITORING

The study may be prematurely terminated at the discretion of JPEO and PI. The Investigator may terminate the study due to concerns of participant safety. The study will be made available for monitoring, auditing, IRB review, and regulatory inspection by providing direct access to study-related source data.

12.1 Monitoring

Sponsor-assigned monitors will conduct regular site visits to the investigational facilities for the purpose of monitoring various aspects of the study, such as assessing participant enrollment, compliance with protocol procedures, completeness and accuracy of data entered into the eCRFs, verification of eCRF data against original source documents, and occurrence of AEs. The Investigator must agree to Sponsor-authorized personnel having direct access to the clinical (or associated) files and clinical study supplies (dispensing and storage areas) to ensure compliance with applicable regulations, and the Investigator will assist with the Sponsor's monitoring activities.

The objectives of a monitoring visit will be:

- To verify the existence of electronically signed informed consent documents and documentation of the informed consent process for each enrolled participant;
- To verify the prompt and accurate recording of all monitored data points and prompt reporting of all SAEs;
- To help ensure Investigators are in compliance with the protocol. The monitors also will inspect the clinical site regulatory files to ensure that regulatory requirements (Office for Human Research Protections), FDA, and applicable guidelines (ICH GCP) are being followed. During the monitoring visits, the Investigator (and/or designee) and other study personnel will be available to discuss the study progress and findings of the monitoring visit.

A specific study monitoring plan will be discussed with the PI and study staff prior to enrollment. The plan will outline the frequency of monitoring visits based on such factors as study enrollment, data collection status, and regulatory obligations. Protocol deviation reporting will be outlined in a study monitoring plan.

Quality control will occur at each stage of data handling to ensure that all data are reliable and have been processed correctly. The Sponsor should ensure oversight of any study-related duties and functions carried out on its behalf, including those that are subcontracted to another party by the Sponsor's contracted CRO(s).

The eCRFs should be completed in a timely manner and on an ongoing basis to allow regular review by the study monitor.

The Investigator (or designee) may interrupt the collection of samples or discontinue the participant from the study, if indicated, for unanticipated problems or AEs. In addition, the Investigators are responsible for:

- Protecting the safety and welfare of participants
- Evaluating participant safety, including physician assessment of AEs for seriousness, severity, and causality
- Notifying the Sponsor of SAEs and immediately reportable events
- Providing detailed written reports, including confirmatory tests promptly following immediate initial reports
- Informing the IRB of SAEs

Details describing the strategy, responsibilities, and requirements of the study monitoring are provided in the study monitoring plan.

12.2 Audits and Inspections

The purpose of an audit is to assess whether ethics, regulatory, and quality requirements are being fulfilled. The Sponsor or its representative may conduct audits at the investigative sites including, but not limited to, supply, presence of required documents, the informed consent process, and comparison of eCRFs with source documents. Government regulatory authorities may also inspect the Investigator during or after the study. The Investigator (or designee) should contact the Sponsor/CRO immediately if this occurs. All medical records (progress notes) must be available for audit. The Investigator must agree to participate with audits conducted at a convenient time in a reasonable manner.

12.3 Risk and Quality Tolerance Limits

Perceived risks and quality tolerance limits (QTLs) will be identified and documented before the start of the study.

The Sponsor will review risk control measures periodically to ascertain whether the implemented quality management activities remain effective and relevant. The quality management approach and any important deviations from the predefined QTLs (and remedial actions adopted) will be described in the clinical study report (CSR).

12.4 Protocol Adherence and Deviations

The Investigator and site personnel should conduct the study in compliance with the protocol and should use continuous vigilance to identify and report protocol deviations.

A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol that may be on the part of the Investigator, site personnel, or the participant.

Important protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data, or that may

significantly affect a participant's rights, safety, or well-being. For example, important protocol deviations may include enrolling participants in violation of key eligibility criteria designed to ensure a specific population, or failing to collect data necessary to interpret primary endpoints, as this may compromise the scientific value of the study.

The Investigator should not implement any deviation from the protocol without agreement from the Sponsor and prior review and approval of an amendment from the IRB/IEC, except where necessary to eliminate an immediate hazard to a study participant, or when the change involves only logistical or administrative aspects of the study, such as a change in a monitor or telephone number.

In the event of an important protocol deviation, the Investigator will discuss the deviation with the Sponsor's medical monitor and will come to an agreement as to whether the participant should be withdrawn from the study due to the important protocol deviation.

13 AMENDMENTS

Protocol modifications, except those intended to reduce immediate risk to study participants, may be made only by the Sponsor. A protocol change intended to eliminate an apparent immediate hazard to participants should be implemented immediately.

Any permanent change to the protocol must be handled as a protocol amendment. The written amendment must be submitted to the IRB/IEC, and the Investigator must await approval before implementing the changes. The Sponsor will submit protocol amendments to the appropriate regulatory authorities for approval.

The current version of the eConsent form will require similar modification if the IRB/IEC, Investigator, and/or Sponsor judge the amendment to the protocol to substantially change the study design and/or increase the potential risk to the participant and/or impact the participant's involvement in the study. In such cases, the eConsent form will be renewed for enrolled participants before their continued participation in the study.

14 STUDY REPORT AND PUBLICATIONS

This study will be registered on ClinicalTrials.gov in accordance with applicable laws or publication policy and may also be registered on other publicly accessible websites as necessary.

The Sponsor is responsible for preparing and providing the appropriate regulatory authorities with the CSR according to the applicable regulatory requirements. The Sponsor should ensure that the CSR meets the standards of the ICH Guideline for Structure and Content of Clinical Study Reports (ICH E3).

The publication policy of the Sponsor is discussed in the Investigator's clinical research agreement.

The results of this study may be published or presented at scientific meetings. If this is foreseen, the Investigator agrees to submit all manuscripts or abstracts to the Sponsor before submission. This allows the Sponsor to protect proprietary information and to provide comments.

The Sponsor will comply with the requirements for publication of study results. In accordance with standard editorial and ethical practice, the Sponsor will generally support publication of multicenter studies only in their entirety and not as individual site data.

Authorship will be determined by mutual agreement and in line with International Committee of Medical Journal Editors authorship requirements.

15 STUDY START AND TERMINATION

The study start date is the date on which the first participant provides informed consent.

The end of the study is defined as the last participant's last assessment.

The study may be prematurely terminated at the discretion of JPEO and PI. The Investigator may terminate the study due to concerns of participant safety. Both the Sponsor and the Investigator reserve the right to terminate the study or the participation in the study at an Investigator's site at any time. In terminating the study, the Sponsor and the Investigator will assure that adequate consideration is given to the protection of the participants' interests.

If the study is prematurely terminated or suspended for any reason, the Sponsor/Investigator/site personnel should promptly inform the study participants and should assure appropriate therapy and follow-up for the participants. Where required by the applicable regulatory requirements, the IRB/IEC should be informed promptly and be provided with a detailed written explanation of the termination or suspension.

If the Investigator terminates or suspends a study without prior agreement of the Sponsor, the Investigator should inform the site personnel. The Investigator/site personnel should promptly inform the Sponsor and the IRB/IEC. The Investigator/site personnel should also provide the Sponsor and the IRB/IEC a detailed written explanation of the termination or suspension.

16 CONFIDENTIALITY

All information generated in this study is considered highly confidential and must not be disclosed to any person or entity that is not directly involved with the study unless prior consent is gained from the Sponsor. However, authorized regulatory officials, IRB/IEC personnel, the Sponsor, and its authorized representatives are allowed full access to the records.

All study participants must be informed that their personal study-related data will be used by the Sponsor in accordance with local data protection law. The level of disclosure must also be explained to the participant, who will be required to give consent for their data to be used as described in the eConsent form. The participants must be informed that their medical records (progress notes) may be examined by auditors or other authorized personnel appointed by the Sponsor, by appropriate IRB/IEC personnel, and by inspectors from regulatory authorities.

Identification of participants and eCRFs shall be by unique identification numbers (such as screening number) only. All personal identifiers according to applicable regulations (eg, name, phone number) must be redacted permanently by the site personnel and replaced with the participant's unique identification number in all records and data before transfer to the Sponsor (or designee).

All personal details will be treated as confidential by the Investigator and staff at ICON.

17 REFERENCES

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18 APPENDICES

18.1 Appendix I – Study Administrative Structure

Sponsor:	Resilience Government Services, Inc. Jordan Bauers, PharmD 13200 NW Nano Court, Alachua, FL 32615 email: Jordan.Mitchell@resilience.com Fax: +1 888 551 1691
Medical monitor:	Robert Spitz, MD, Medical Director ICON plc
CRO:	ICON plc Corporate Headquarters South County Business Park Leopardstown, Dublin 18 Ireland Phone (IRL): +353 1 291 2000 Phone (US): +1 215 616 3000 Fax: +353 1 247 6260
Central laboratory:	Brendan McLoughlin, Director, Laboratory Operations ICON plc

A log of the name and title of the Investigators who are responsible for conducting the study, and the addresses and telephone numbers of the clinical sites will be maintained.

18.2 Appendix II – Non-Significant Risk Letter

Tasso

March 22nd, 2022

RE: A clinical study to evaluate the performance of the Tasso family blood collection platform

To whom it may concern,

This letter is to justify that the Tasso medical device involved in the submitted IRB study is a non-significant risk (NSR) device as it does not meet the definition of significant risk (SR) as defined by 21 CFR 812.3(m), and meets the Abbreviated IDE requirements in accordance with 21 CFR 812.2(b). The following criteria support the NSR status of the Tasso device:

- A lancing device, which is the blood collection component of the Tasso device, is an FDA Class II device (see FDA 21 CFR 878.4850) which does not present a potential for serious risk to the health, safety, and welfare of a subject and is not an implant, used in supporting or sustaining human life, or of substantial importance in diagnosing, curing, mitigating, or treating disease or preventing impairment of human health.
- The Tasso device is designed and manufactured in accordance with ISO 13485 and 21 CFR 820, including verification and validation of device safety, sterility, shelf-life, biocompatibility, and packaging.
- The Tasso device is designed based on commercially available blood lancets on the market with lancing parameters similar in length, depth, and materials.
- The Tasso device presents low risk to the subjects in the study as the procedures involved are common lancet punctures. Tasso has applied over 100,000 Tasso-SST and 10,000 Tasso+ on subjects since 2014 without any significant adverse events recorded.
- Blood sample collection with the Tasso device will not exceed 1 mL.
- The Tasso device has been utilized in a number of IRB approved studies as an NSR device.

Thank you for your consideration,

Erwin Berthier
CTO
Tasso, Inc

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