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Study Manual

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1. Introduction

The purpose of this document is to describe responsibilities, project team structure, timeline, major deliverables management, communication, training, and any project-specific processes and procedures. The clinical trial participating sites are Tel-Aviv University, Tel-Aviv Surasky medical center (TASMC), National and Kapodistrian the University of Athens (NKUA), Vilnius University Hospital Santaros Klinikos (VULSK), Faculty nemocine Olomouc (FNO), Palacky University (UP) and JaxBio Technologies Inc.

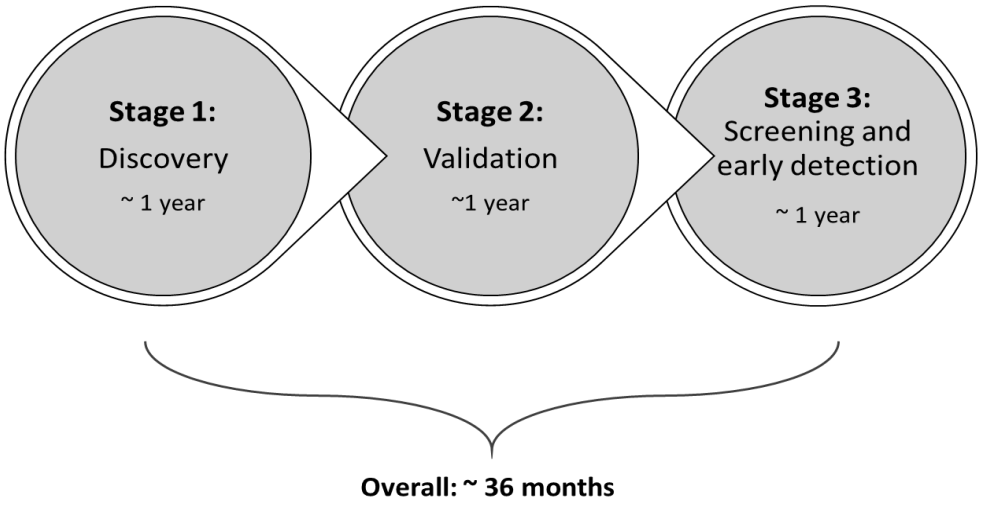
2. Project Scope

The aim of SANGUINE project is to develop a novel tool for early detection and screening of blood cancer. The project involves the collection of blood samples from subjects diagnosed with various types of hematological cancers or pre-malignant conditions, follow-up subjects, individuals at-risk of developing hematological malignancy and control subjects with no malignant disease.

3. Work Plan

3.1. Timeline

A detailed project timeline has been developed. The timeline contains project dates and deliverable deadlines involving the entire project team. This timeline will be referenced throughout the study, during project team meetings and discussions. Any updates from the project team to the timeline should be directed to the coordinator or designee. Overall, the project is divided into three main stages:



3.2. Study administrative team

CRO services and project management are provided by the Clinical Trials Unit of the division of Hematology at Tel-Aviv Sourasky Medical Center and by Titania technologies BV. Each clinical center consists of a project partner and study personnel familiar with the ICH-GCP guidelines. The CRO companies will ensure the quality of the data, adherence to timelines and compliance with ICH-GCP guidelines.

3.3. Subject recruitment

The treating oncologists will recruit subjects at diagnosis/follow-up with one of the conditions described in the study protocol. During the recruitment process, the oncologist will inform the subject of the study, provide information, and answer questions raised by the subjects or family members. The oncologist will then ask the subject to read and sign a consent form. Only subjects eligible for the study will be recruited (eligibility will be determined by the inclusion and exclusion criteria, refer to study protocol). In any doubt regarding the subject's eligibility, the sites will make a formal query to the project coordinator or designee. The project coordinator (or designee) will determine whether the subject is eligible or not.

3.4. Meeting the recruitment goal

The screening, enrollment and blood collection for all stages can begin in the first stage of the trial, in order to meet the recruitment goals. Any of these should be followed by the instructions of sections 7 and 9 of this document.

3.5. Control subjects (with no malignant disease) and subject at risk to develop MM / lymphoproliferative disorder

A questionnaire to record medical history should be completed by the Investigator and data should be recorded in the eCRF. Refer to Annex 2 and eCRF completion guidelines.

4. Communication

4.1. Contact list

The dynamic and living contact list (Annex.1) will be maintained and distributed to all clinical sites during the trial. It is the responsibility of the team members to update regarding any changes in the team or contact details.

4.2. Daily communication

- Investigators are instructed that the CRAs are their primary contacts for all practical issues or questions regarding the conduct of the study. All medical queries and protocol questions (including eligibility) should be sent to the CRA.

- A 'Frequently Asked Questions & Answers' document (FAQ) is maintained and distributed to the clinical sites periodically.

4.3. Ways to communicate

The coordinator shall ensure regular communication with the project partners and provide information on the study's progress. The following forms of communications can be used:

- Regular teleconferences with minutes provided by the CRO.
- Newsletters from the coordinator or designee to the clinical partners.

- Emails.
- Face-to-face ads remote meetings.

4.4. Issue escalation and resolution

4.4.1. Purpose of issue escalation

The purpose of issue escalation is to raise emerging and/or unresolved issues to the Coordinator attention for timely resolution. The coordinator is encouraged to identify issues proactively. Events that may require escalation include, but are not limited to:

1. Project status issues

- Timeline concerns
- Site recruitment issues
- Subject enrolment issues
- Quality or compliance issues
- Site resource issues
- Notification of regulatory inspections at a site

2. Communication issues

4.4.2. Issue escalation and resolution process

1. If issues arise during study conduct, the appropriate primary contacts at the sponsor\ project management group should be notified by phone and/or e-mail.

2. Procedures/steps to be taken to resolve the issue will be discussed between the respective clinical site and the coordinator / designee and documented by email, including:
   - Resolution plan
   - A timeframe in which to resolve the issue
   - Person(s) responsible for the resolution of the issue

5. Electronic Case Report Form (eCRF)

The principle investigator is responsible for the accuracy, authenticity, timely collection, and reporting of all clinical, safety and laboratory data entered into the eCRFs. All these data may only be entered into the eCRF by authorized qualified trial personnel by the timeline mentioned in this document. The data collected in the eCRFs must match with the data in the source documents.

5.1. Data entry into the eCRF

The trial's eCRF will be filed electronically using the RedCap software. All partners that are in need to have access to the clinical data should hold up-to-date and active users. The users will be then approved by the CRAs and will be able to complete the eCRF according to the CRF completion manual. eCRF should be completed with updated data weekly by Thursday 8:00 PM (site's local time). An explanation should be given for all missing data. For complete instructions please refer to the eCRF completion guidelines.

6. Subject Identification Number

The subject identification number is a 7 to 8-digit subject number consisting of 3 parts:

1. **Initial number**: a one-digit letter will be assigned by the coordinator at each clinical site according to the facility's name. Each site will be informed before trial initiation, with its site identification. Site letters are:

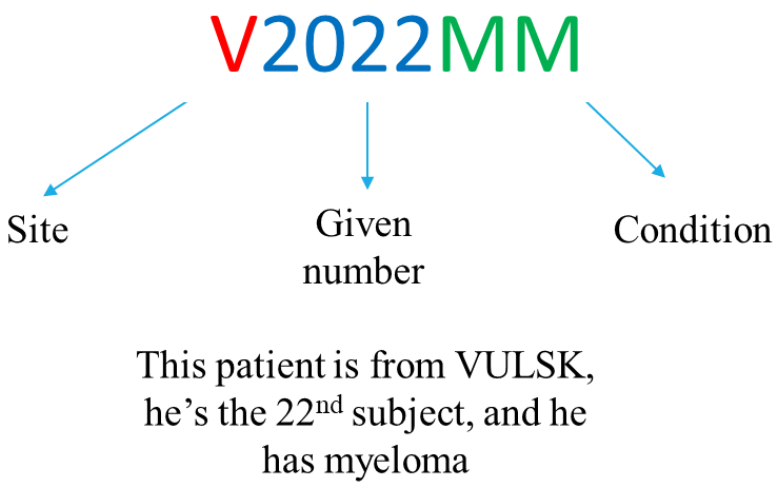
- TASMC – T
- VULSK – V
- NKUA – N
- FNO – F

2. **Subject number:** a 4-digits numerical subject number will be provided to the clinical sites in advance in an excel table by the coordinator. The table consists of subsequent numbers, and each subject will be assigned a number according to the order of their inclusion in the study. Subject number is not subjected to any changes without the CRO approval. Each site will get 500-1,000 subject numbers in advance.

3. **Haematological condition marking:** the last 2 to 3-digits of the subject number will describe his/her hematological condition. These digits will be provided by the coordinator:

1. **MM** for Multiple Myeloma
2. **MG** for MGUS
3. **SMM** for Smoldering Myeloma
4. **HL** for Hodgkin Lymphoma
5. **DLB** for DLBCL
6. **AML** for Acute Myeloid Leukaemia
7. **MZL** for Marginal Zone Lymphoma
8. **FL** for Follicular Lymphoma
9. **MDS** for Myelodysplastic syndrome
10. **AR** for designated subjectsat risk to develop MM / lymphoproliferative disorder. (Elderly >65 and/or first degree relatives). Relevant only in stage3 for specific sites.
11. **C –** for control subjects without haematological malignancy who will serve as the control group for the discovery phase.

An example for subject ID:



6.1. How to allocate subject number

- Each site will receive 500-1,000 subject numbers in an Excel file. Generally:

1. TASMC will get numbers from 0001 to 1000
2. VULSK will get numbers from 2500 to 2999
3. NKUA will get numbers from 3500 to 4000
4. FNOL (UP) will get numbers from 5000 to 6000

- Once assigned, a subject number will not be reused. If the subject fails to enter the study for any reason his/her number will be highlighted in red and its status will be marked as in "screen failure".

Using the "Subjects Numbers" excel sheet

1. Once a subject is included in the study , the site staff will assign him/her with a number (example is given in the next few figures):

Site Code	subject Number	Condition	Date of visit	RedCap link	Status	Age	Stage	Visit #
T	0109							

2. Next, please choose from the list the Subject's condition:

Site Code	subject Number	Condition	Date of visit	RedCap link
T	0070			
T	0071	MM MG SMM		
T	0072			

3. Next, fill in all the relevant data, including the date of visit, a link for the subject's CRF in RedCap and its status (choose from the list):

4.

Site Code	subject Number	Condition	Date of visit	RedCap link	Status	Age
V	2500					
V	2501					
V	2502					
V	2503					
V	2504					
V	2505					
V	2506					
V	2507					

Enrolled
Screen failure
Excluded

5.

NOTE: If the subject signed the ICF form, blood wasn't taken yet, and the subject cannot be enrolled to the study for some reason- please fill "**Screen failure**" in the Status column. If the subject signed the ICF, blood was collected, and the subject cannot be enrolled to the study for some reason- please fill "**excluded**" in the status column.

6. Once the subject is enrolled, he will be assigned to a stage in a trial. please make sure to record the stage in the excel correctly (choose from the list):

Site Code	subject Number	Condition	Date of visit	RedCap link	Status	Age	Stage
T	0067	MZL	15/05/2023	SANGUINE | REDCap (tasmc.org.il)	Enrolled	75	
T	0068						
T	0069						

1
2
3

5. Please fill the visit number in the table. For stages 1 and 3 choose "Baseline" from the list. For stage 2- for the first visit choose "Baseline", for the follow up visits choose "F1", "F2" etc.

Site Code	subject Number	Condition	Date of visit	RedCap link	Status	Age	Stage	Visit #
T	0107	DLB	28/07/2023	https://redcap.tasmc.org.il/redcap_v12.5.17/DataEntry/record_home.php?pid=1	Enrolled	75	1	Baseline
T	0108							
T	0109							
T	0110							
T	0111							
T	0112							
T	0113							

Baseline
F1
F2
F3
F4
F5
F6
F7

6. Please fill the "consent for other studies" column, by filling "Yes" or "No". This column refers to the additional consent that is not mandatory.

Site Code	Condition	Date of visit	RedCap link	Status	Age	Stage	Visit #	consent for other studies
T	DLB	06/08/2023	https://redcap.tasmc.org.il/redcap_v12.5.17/DataEntry/record_home.php?pid	Enrolled	75	1	Baseline	Yes

7. If the sample is processed on site, please fill columns K-Q:

K	L	M	N	O	P	Q
was sample processed on site?	Plasma separation date	Plasma separated by	Total plasma volume separated (ml)	Frozen plasma volume-tube 1 (ml)	Frozen plasma volume-tube 2 (ml)	Buffy coat separated?

8. Please fill column R-S for Stage 3 only.

R	S
For stage 3 only	
Myeloma profile	Results

9. If the subject is assigned for another stage, please fill the subject's details in two different rows, each row for a different stage:

Site Code	subject Number	Condition	Date of visit	RedCap link	Status	Age	Stage	Visit #
T	0131	C	05/09/2023	https://redcap	Enrolled	63	1	Baseline
T	0131	C	05/09/2023	https://redcap	Enrolled	63	3	Baseline

Additional excel sheets that you should use:
Excel for labels of processed samples (for printing the labels) and ID log excel.

7. Laboratory - HemaChip

7.1 Samples collection

Blood Samples: blood for HemaChip tests will be collected in two cell-free DNA BCT tubes by STRECK. Full protocol (can be found online) described here:

1. Collect specimen by venipuncture according to CLSI GP411.

2. Prevention of Backflow - Since Cell-Free DNA BCT contains chemical additives, it is important to avoid possible backflow from the tube. To guard against backflow, observe the following precautions: a. Keep subject's arm in the downward position during the collection procedure. b. Hold the tube with the stopper in the uppermost position so that the tube contents do not touch the stopper or the end of the needle during sample collection. c. Release tourniquet once blood starts to flow in the tube, or within two minutes of application.

3. Follow recommendations for order of draw outlined in CLSI GP411. Cell-Free DNA BCT should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Cell-Free DNA BCT tube immediately follows a heparin tube in the draw order, Streck recommends collecting a nonadditive or EDTA tube as a waste tube prior to collection in the Cell-Free DNA BCT.

   NOTE: When using a winged (butterfly) collection set for venipuncture and the Streck Cell-Free DNA BCT is the first tube drawn, a non-additive or EDTA discard tube should be partially drawn first in order to eliminate air or "dead space" from the tubing

4. Fill tube completely.

5. Remove tube from adapter and immediately mix by gentle inversion 8 to 10 times. Inadequate or delayed mixing may result in incorrect analytical results or poor product performance. One inversion is a complete turn of the wrist, 180 degrees, and back. At first label the tubes with the hospital identifier. When it is possible, labels the tubes as described in section 8.

6. After collection, transport and store tubes within the recommended temperature range (6 °C to 37 °C).

7.2 Blood samples processing

Blood samples processing for the discovery stage of the trial will be done at the central lab. Once the HemaChip is distributed to the sites, processing of sample from STRECK tubes will be done by the sites as follows:

1. Prepare labels in advance according to section 8 of this manual.

2. Centrifuge the blood tubes at 1,600 xg for 10 minutes, with Deceleration 3.

   Important!
   Use the swing bucket rotor. Apply Dec 3 to avoid mixing of the plasma with the buffy coat, which will result in contamination of the plasma with genomic DNA.

3. Transfer the upper layer (that contains the plasma) carefully to a new 15 ml falcon tube. **Do not** take the white layer that contains WBC.

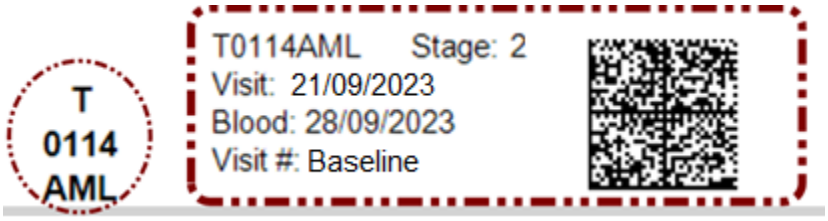
4. Take each Streck tube and carefully transfer the buffy coat layer (the white ring situated between the blood and the plasma) to new 1.5 ml tubes. When collecting the buffy coat layer, it's OK if a small amount of red blood cells are also collected in the process. The final collection volume should be approximately 800-1000 µl. Vortex the newly filled tubes briefly to ensure homogeneity. Transfer 200 µl* from each of these tubes to separate new tubes while retaining the rest of the buffy coat in the original tube. Label each tube with two labels. The side label should contain the visit date, extraction date, subject serial number, type of sample (Blood), stage, visit # and a QR code. (The QR code is generated from the

REDCap link, and when scanned- it directs to the sample data on REDCap). The label on the lid should contain the subject serial number. Freeze at -20 °C.

5.

6. * The tube containing 200 microliters of the buffy coat is designated for the initial input required for DNA extraction. This approach ensures that we don't have to thaw the entire volume collected from the Streck tube. If a larger amount of DNA is needed, then the tube containing the remaining buffy coat can be thawed gradually.

Example of the label template:



7. Centrifuge the plasma (upper layer from step 3) at 5,000 xg (or maximal speed) for 10 min.

8. If there is a small white layer on top of the plasma, remove and discard it.

9. Transfer the purified plasma to new 15 ml falcon tubes, ~5 ml per tube, without touching the pellet on the bottom of the tube. Label the tubes with two labels. The side label should contain the visit date, plasma purification/extraction date, subject serial number, type of sample (Plasma), stage, visit # and a QR code. The label on the lid should contain the subject serial number. Freeze the purified plasma at -80 °C.

10. Instructions for cell-free DNA extraction and genomic DNA extraction will be given at stage II of the project, as part of a comprehensive training.

7.3 Samples storage

1. STRECK tubes: Blood in STRECK tubes can be kept at room temperature up to 10 days (including shipment time).

2. Processed samples:

a. Plasma samples will be kept in 15 ml falcon tubes at -80 ^{0}C.

b. Blood samples (buffy coat) will be stored at -20 ^{0}C.

c. cell-free DNA and genomic DNA will be kept at 4 ^{0}C. For long term storage it is recommended to freeze DNA samples.

7.4. Waste disposal

7.4.1. **STRECK tubes**- Glass containers are considered as sharps and must be discarded in an approved sharps container. Dispose of unused BCTs as nonhazardous waste. Dispose of used BCTs in same manner as patient sample. Sharp containers are either autoclaved or decontamination of the contents can be accomplished by chemical means (for example using

10% bleach).

7.4.2. **Human blood and blood products:** The waste must be decontaminated by autoclave, chemical disinfection or other appropriate decontamination method. If the treatment of choice is a validated decontamination procedure, the waste will be labeled as "non-biohazardous/non-infectious" and can go as regular trash.

7.5. Additional lab tests

For subjects at risk, additional lab tests will be conducted. The required lab tests will be the following:

- Full chemistry
- Complete blood count
- Free Light Chain (FLC) test
- Serum Protein Electrophoresis (SPEP)

The results should be documented in the eCRF according to the CRF completion guidelines.

8. Labeling and Barcoding

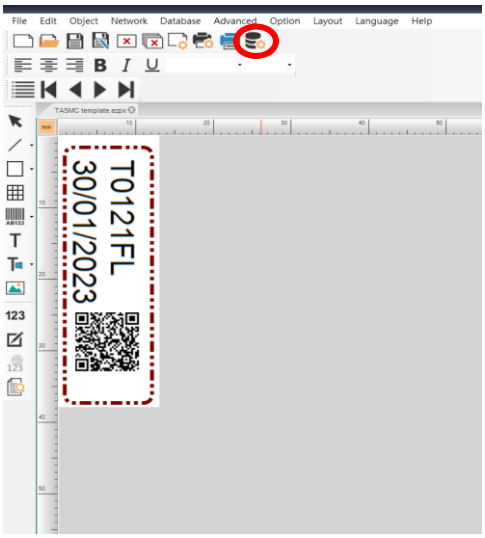
Each STRECK tube should be labeled with the specific label for the SANGUINE trial. Labeling will be done in the assistance of GoLabel software.

8.1. Template and loading Excel sheet

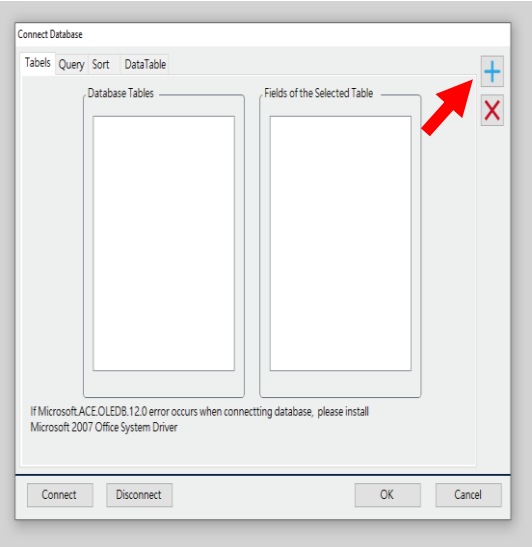
The CRO will provide the sites with templates for use at all study stages. On stage I of the project, a template for Streck tubes is needed. In the advance steps, templates for processed samples are required. The workflow below is shown with the Streck tube template. Here are the steps:

1. Open the template.

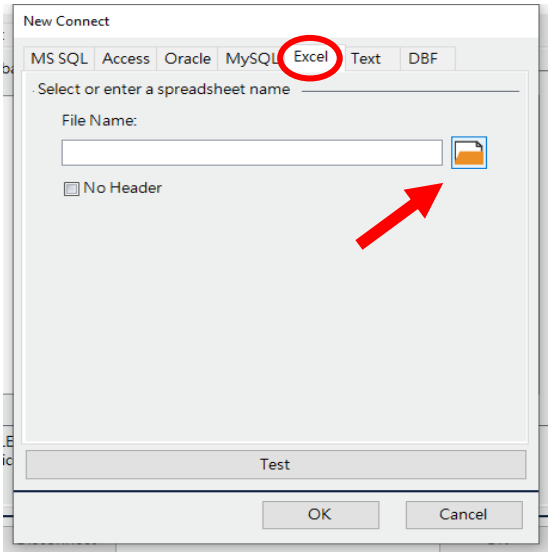
2. At first, load the excel file to the template. To do so, press the “Barrel” icon at the top:



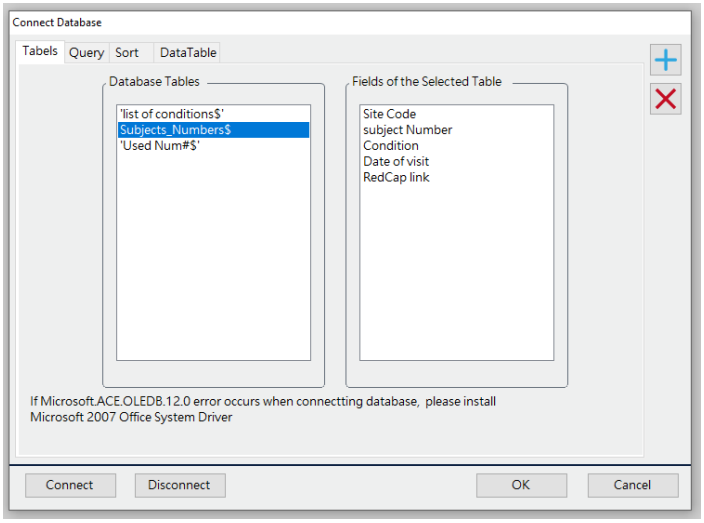
2. Now a window will pop-up, press on the blue “+” button:



3. A new window will pop-up; please select the Excel tab and then press the folder button and choose the excel file:



4. Now, on the left side of the window the sheets of the excel will appear. Please press with the pointer on “Subjects_Numbers” and then press “ok”:

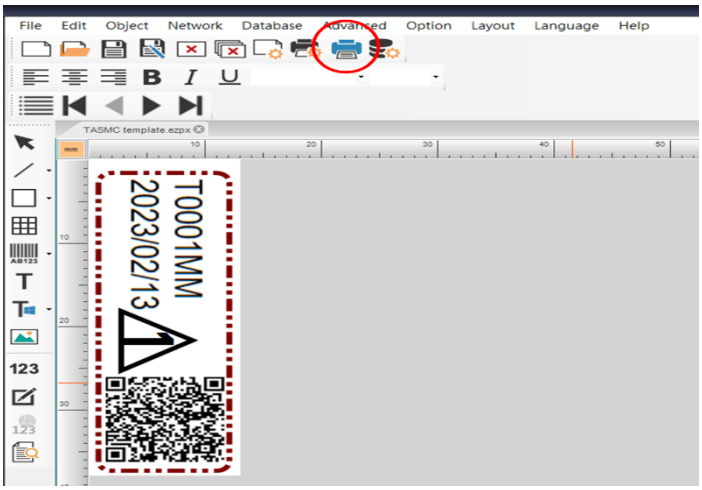


NOTE: For the processed samples template, choose "Sheet1" in this window.

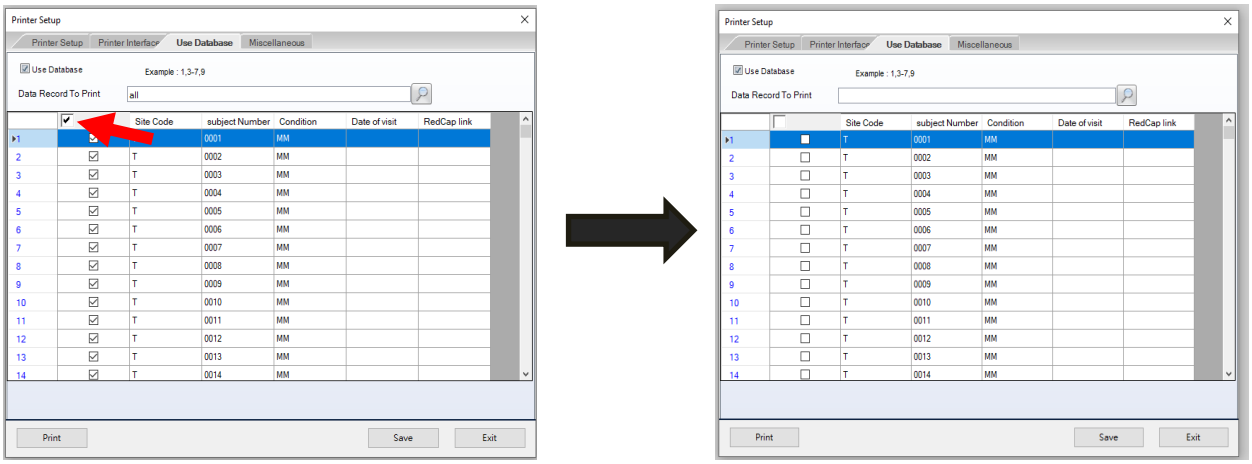
*there is no need to repeat stage 1-4. Please make sure to save the excel file **before** launching the "GoLabel" software.

8.2. Printing the labels

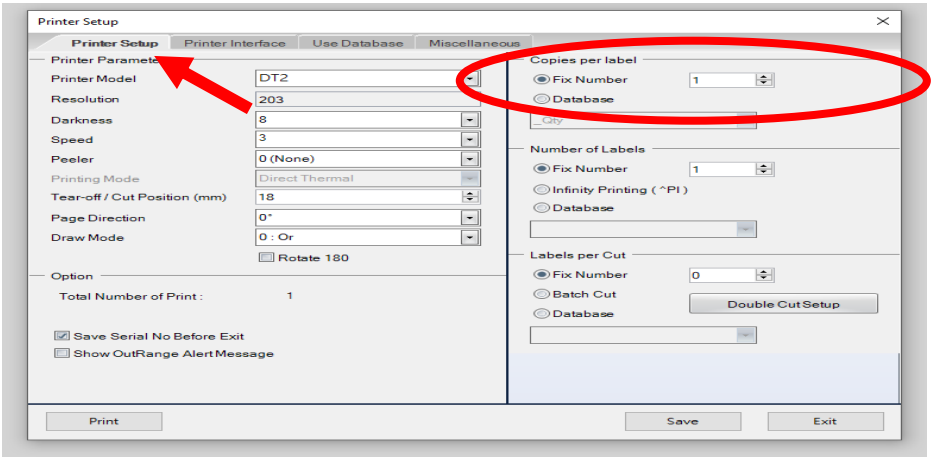
1. Print each label 3 times: one for each STRECK and one will be kept for the Requisition form. To print the labels, choose the row visually from the table in the software. first press the blue printer icon:



2. Make sure to un-tick the √ at the top of the table in order to unselect all:



3. Once the needed subject is found, tick a √. Before printing, please make sure you choose the right amount of copies you wish to print:



4. Hit the "print" button and label the tubes.

<u>MAKE SURE THAT THE SHIPMET MATERIALS DON'T INCLUDE ANY SUBJECT IDENTIFIERS (e.g., name, ID number, date of birth, address, etc.)</u>

9. Instructions for Shipment of Blood Samples

9.1. Samples preparation for shipment

Place each STRECK tube into a 50 ml falcon tube. After insertion, add pieces of paper to hold the blood tube in place and to avoid shaking of the tube. Place the tubes of each subject in a padded plastic bag contains the requisition form. Place of all of the plastic bags in a sealed plastic box.

9.2. Samples shipment condition and temperature

1. STRECK tubes: will be sent ambient
2. Plasma samples: will be sent in dry ice
3. Frozen blood / buffy coat will be sent in dry ice
4. DNA will be sent with coolers

9.3. Shipment frequency

1. **First stage of the clinical trial (discovery):** shipment to the central lab will be carried out within 7 days of collection.

2. **Stages two (validation) and three (early detection):** shipment to the central lab will be carried out upon request, fresh (within 7 days) or frozen.

9.4. Requisition form

A requisition form (Annex.3) will be filled out and attached to each sample shipped to the central lab. Please note:

1. Stages 1 and 2-3 of the clinical trial has two different requisition forms:
   - SANGUINE_Laboratory Requisition Form_**Stage 1**
   - SANGUINE_Laboratory Requisition Form_**Stages 2-3**

2. Fill the requisition form, label it in the designated space with the subject's label, sign it and scan it. Please keep all scanned forms in a designated binder at the site.

3. Place the original forms in a bag contains its matching samples and send with the samples.

4. A team member in the central lab will confirm receipt of samples by signing the requisition form. The signed forms will be kept by JaxBio.

9.5. Shipment courier and airway bills

The international courier for this project is Fedex. Shipments will be billed to JaxBio Ltd. and shipments costs will be charged from JaxBio account. The clinical site will provide a contact person to be in charge of shipment preparation, coordination and contact with JaxBio. Once the samples are ready for shipment, the clinical partner will contact JaxBio (office@jaxbio.com) to set a date for shipment. JaxBio will coordinate the pick-up and will issue an airway bill and invoice that will be sent via email to the clinical site. In principle, the clinical sites should contact JaxBio on Tuesdays and shipments should be picked-up on Thursdays. For urgent issues regarding shipments please contact Hila Erez via WhatsApp, Tel: +972-54-4231013.

9.6. Shipment Procedure

1. Contact JaxBio 2 days before shipment (on Tuesday each week) in order to set the delivery date (on Thursday). Inform how many tubes are intended to be shipped. In case there is a change in the number of tubes before the package is out for delivery, update JaxBio via email. JaxBio will update the invoice.

2. Wrap all the sample as described in section 9.1

Print the updated airwaybill and invoice that was sent by JaxBio and hand it to the courier with the package.

All samples will be sent to the central lab in JaxBio Technologies.
Address: Giborei Israel 7, entrance B, third floor, Netanya, Israel. 4250407. ATTN: Hila Erez, Tel: +972-54-4231013

Annex. 1– Contact list

Name	Role	Email address	Phone Num.
Yuval Ebenstein	Project coordinator	yebenstein@gmail.com	+972-3-6408901 +972-54-3188316
Noa Lowenton Spier	Project management, Head of clinical trials unit TASMC	noals@tlvmc.gov.il	+972-52-5527553 +972-3-6947824
Helena Grinberg-Rashi	Supervisor CRO	lenagrin@gmail.com	+31-6-1563-6666 +972-52-855-1179
Yoram Lev Yehudai	Financial coordinator	yly@orientos.com	+370-615 55866
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Mor Levi	SI	morle@tlvmc.gov.il	
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Andrejus Cernovas	Study Coordinator	Andrejus.Cernovas@Santa.Lt	+37068861548
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Annex.2 – Medical history questionnaire

SANGUINE

Funded by the European Union

LABEL WITH SUBJECT'S NUMBER HERE

SANGUINE Project – Control/ At risk subjects questionnaire, to be filled by an investigator:

1. Subject's Gender? ☐ Male ☐ Female
2. Weight (Kg.):_____ Height (Cm.) : _____
3. Race: ☐Caucasian ☐Asian ☐Black ☐Other:_____
4. Subject's date of birth: _____
5. Has the subject ever been diagnosed with cancer? ☐ Yes ☐No
6. If "Yes", when? _____
7. If "yes", what type of cancer? _____
8. If in complete remission- when was the complete remission (month and year):_____

- In case of active cancer, the subject cannot be enrolled.
- If the subject has undergone remission within the last 2 years, the subject cannot be enrolled (Exceptions: Melanoma/Carcinoma that were removed entirely).

9. Has one of their first-degree relatives been diagnosed with Hematological cancer? ☐ Yes ☐No
10. If "yes", what type of cancer? _____
11. Is the subject currently diagnosed with active inflammatory autoimmune disease that requires treatment with immunosuppressive/ immunomodulation agents? ☐ Yes ☐No

- If "Yes," the subject cannot be enrolled

12. As far as you know, are you positive for HIV? ☐ Yes ☐No

- If "Yes," the subject cannot be enrolled

13. As far as you know, are you positive for Hepatitis A/B/C or was positive to Hepatitis C? ☐ Yes ☐No

- If "Yes," the subject cannot be enrolled

14. Do you smoke? ☐ Yes ☐No
15. Did you smoke in the past? ☐ Yes ☐No

For how many years? _____ packs per year: _____

16. Any concomitant medications? ☐ Yes ☐No

Trade name: _____ dosage: _____ frequency: _____ start date: _____
Trade name: _____ dosage: _____ frequency: _____ start date: _____
Trade name: _____ dosage: _____ frequency: _____ start date: _____

17. Any relevant medical history?

	Start date	End date
Diabetes mellitus		
Obesity		
Hypertension		
Myocardial ischemia		
Cardiac failure		
Chronic respiratory disease		
Other:		

Physician Signature and Stamp + date

_____

Annex.3 – Requisition forms

LABORATORY REQUISITION FORM

Ship to: Giborei Israel 7, entrance B, third floor, Netanya, Israel. 4250407. ATTN: Hila Erez, Tel: +972-54-4231013	SANGUINE	**Attach Here STRECK Tube Label**
STAGE 1	Page 1 of 2	

ALL INFORMATION IS REQUIRED

Subject ID #: (Example: T0021MM, derived from the "subjects excel sheet")	☐☐☐☐☐☐☐☐ (Site / Subject Number / Condition)
Subjects date of birth: Not mandatory if the field of age was filled	☐☐-☐☐-☐☐☐☐ (Day / Month / Year)
Age:	☐☐
Gender:	☐ F ☐ M
Sample Collection Date:	☐☐-☐☐-☐☐☐☐ (Day / Month / Year)
Visit number: *For FU subjects label F1, F2, F3…for each visit after baseline visit	☐ (Baseline) F ☐ (Only for FU subjects)
Shipping Date: (shipping should be executed within 7 Days of collection)	☐☐-☐☐-☐☐☐☐ (Day / Month / Year)

ATTENTION! EACH VISIT/TIMEPOINT CONTAINS TWO STRECK TUBES. TUBES ARE KEPT AT ROOM TEMPERATURE

For any questions, please contact: lenagrin@gmail.com, +31-6-1563-6666

TO BE FILLED BY THE SITE

Filled by:_____ (Print Name) **Role:**_____

Date: _____ **Signature:**_____

TO BE FILLED BY CENTRAL LAB

Accepted by:_____ (Print Name) **Role:**_____

Date: _____ **Signature:**_____

1. **Please attach a copy of this form to the shipment.**
2. **Please scan this form and send it via email to the address mentioned above.**
3. **Please attach the original form to the patient's file.**

LABORATORY REQUISITION FORM

Ship to: Giborei Israel 7, entrance B, third floor, Netanya, Israel. 4250407. ATTN: Hila Erez, Tel: +972-54-4231013	SANGUINE	**Attach Tube Label Here**
STAGES 2-3	Page 1 of 2	

ALL INFORMATION IS REQUIRED

Subject ID #: (Example: T0021MM, derived from the "subjects excel sheet")	☐☐☐☐☐☐☐☐ (Site / Subject Number / Condition)
Subject Date of Birth: Not mandatory if the field of age was filled	☐☐-☐☐-☐☐☐☐ (Day / Month / Year)
Age:	☐☐
Gender:	☐ F ☐ M
Sample Collection Date:	☐☐-☐☐-☐☐☐☐ (Day / Month / Year)
Back-up Sample:	☐ (Fresh) ☐ (Frozen and processed)
Visit number: *For FU subjects label F1, F2, F3…for each visit after baseline visit	☐ (Baseline) F ☐ (Only for FU subjects)
Shipping Date: (shipping should be executed within 7 Days of collection)	☐☐-☐☐-☐☐☐☐ (Day / Month / Year)

ATTENTION! STRECK TUBES ARE SHIPPED AT ROOM TEMPERATURE AND PROCESSED SAMPLES IN DRY ICE

For any questions, please contact: lenagrin@gmail.com, +31-6-1563-6666

TO BE FILLED BY THE SITE

Filled by:_____ (Print Name) **Role:**_____

Date: _____ **Signature:**_____

TO BE FILLED BY CENTRAL LAB

Accepted by:_____ (Print Name) **Role:**_____

Date: _____ **Signature:**_____

1. **Please attach a copy of this form to the shipment.**
2. **Please scan this form and send it via email to the address mentioned above.**
3. **Please attach the original form to the patient's file.**