



Site Initiation Presentation
May - 2022

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www.lasos-study.org



@LASOS_STUDY



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@lasos_study

Why?

Our aim is to conduct a seven-day cohort study of adults undergoing in-patient surgery in Latin America to provide detailed data describing post-operative complications and associated mortality.

Who?

We will include all adult patients (≥ 18 years) undergoing in-patient surgery during the seven day study period.

How?

We will collect baseline data in operating room and follow patients in hospital for complications (max 30 days)

When?

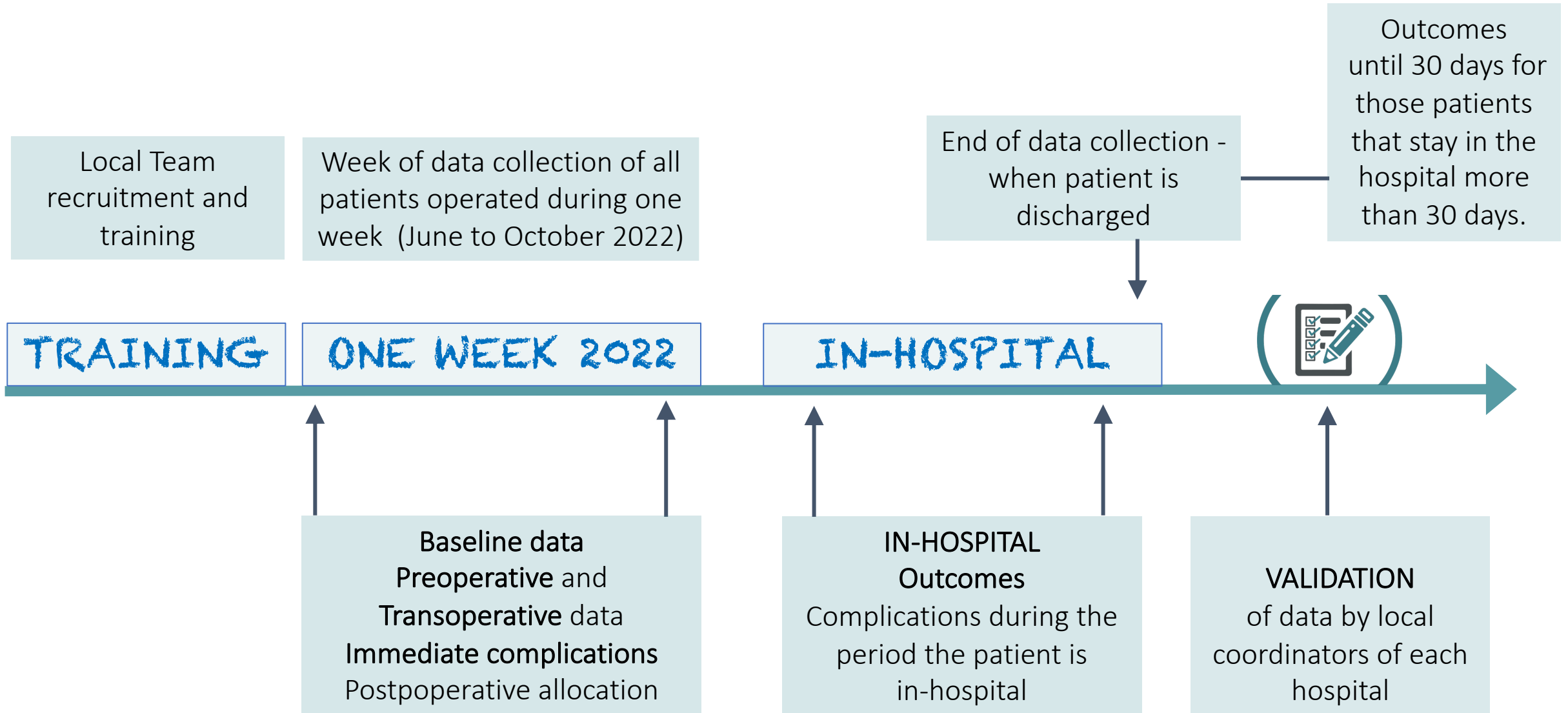
During one week between May-October. Hospitals can start when ethical approval is in place and the documentation has been sent to central administration.

STUDY INITIATION

- ✓ Local leaders inform their interest in taking part to National Coordinators
- ✓ Local leaders provide local ethical approval and inform the National Coordinators
- ✓ National Coordinators inform the list of Hospitals with general information about hospitals that will take part and the name/e-mail of local leaders to be included in the website by the central organization
- ✓ Local leaders (principal investigators of each hospital) will find their institution in the website and will receive an e-mail with a password to access the database
- ✓ Local teams will find their country and hospital in the website and register their names
- ✓ Hospital leaders will approve their own team and they will receive a password
- ✓ Each local team member will be able to complete electronic CRF for each patient.

Only those registered on the website will be included as LASOS members

STUDY PATHWAY



STUDY TRAINING

Local teams should access and read the study documents available at <https://lasos-study.org/>



Home
About the Study
Study structure
LASOS Collaborators
Data Entry
Study Documents
Site training
Contact Us

Click below to download study documents

Study Protocols

-  Study Protocol in English (Jan '22)
-  Study Protocol in Spanish (Jan '22)
-  Study Protocol in Portuguese (Jan '22)

CRFs





-  Study Case Record Form in English (Apr '22)
-  Study Case Record Form in Spanish (Apr '22)
-  Study Case Record Form in Portuguese (Apr '22)

Site training resources

Slides

-  LASOS Slide set in English
-  LASOS Slide set in Spanish
-  LASOS Slide set in Portuguese

Documents

-  Guidance for completing the CRF
-  Definition of complications
-  LASOS Study Administration Structure
-  LASOS Study Local Structure

[Home](#)[About the Study](#)[Study structure](#)[LASOS Collaborators](#)[Data Entry](#)[Study Documents](#)[Site training](#)[Contact Us](#)

Welcome to the Latin American Surgical Outcomes Study (LASOS)

LASOS is an international, investigator initiated, observational seven-day cohort study using routinely collected, anonymised data to confirm the incidence of 30-day in-hospital complications following elective or emergency in-patient surgery in Latin American countries.

LASOS will take place in countries and dependencies in Latin America that are situated in the area stretching from the northern border of Mexico to the southern tip of South America, including the Caribbean. The study is expected to launch in 2022 with each nation selecting a seven-day recruitment period between 1st April and 31st October 2022. During this period, all participating hospitals within that nation will collect data on all eligible patients. There are centres in Argentina, Brazil, Chile, Colombia, Ecuador and Uruguay that have already expressed their interest in taking part in LASOS with many more Latin American nations expected to join.

As the study progresses, the website will be regularly updated with the latest news and documents for you to freely access. To receive even further updates, please follow us on twitter @LASOS_STUDY. For any study related queries, please directly contact the study management team.

Best wishes,

The LASOS Study team

Last updated - 2022-01-20

STUDY DATABASE

www.database.lasos-study.org/



LASOS

[Register](#)

[Reset password](#)

Welcome to the LASOS study
Please log in to access the site.

LASOS

Latin American Surgical Outcomes Study

STUDY DATABASE

www.database.lasos-study.org/



Hospital leaders (principal investigators of each hospital) will be registered by the LASOS central administration and will receive an e-mail with a password to access the database



Local investigators of each hospital will find their institution in the website and should register themselves



Hospital leaders (principal investigators of each hospital) will approve their own team


STUDY DATABASE

To validate a local collaborator



The principal investigator (PI) of each hospital will validate each member of their local team



 LASOS

[Add patient](#) [Search by ID](#) [Worklists](#) [Admin](#) [Superadmin](#)

PI of each hospital user

User administration

25 records per page

Search:

Edit hospital information

User validation

Registered users

Investigator email lists

Registered hospitals

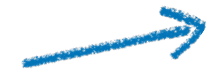
Add a hospital

Selected

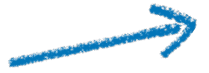
data entry access

Name	Email	Centre	Select
Bianca Stefani	2026bstefani@jpsul.com.br	Hospital de Clínicas de Porto Alegre	<input checked="" type="checkbox"/>

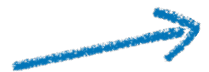
LOCAL TEAMS REGISTER



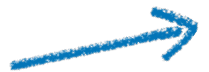
Access the website for the first time (database.lasos-study.org/). Click **REGISTER**
You will find your country and your hospital (if already registered) in the website.



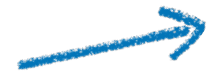
You must register yourself with your **correct name** (given name=first name and family name) as you want to appear cited.



Hospital leaders will approve the names of their team



Local teams will receive a password by e-mail



Each local investigator team member will be able to complete **electronic CRF** for each patient in the field **ADD a PATIENT**.

LOCAL TEAMS REGISTER

Register for the site

Please complete the form below and submit it, registration is not automatic and may take up to 5 working days

→ Given name

→ Family name

→ Email

Country

Centre

Are you the principal investigator for this hospital? ☐ Yes ☒ No ←

Please complete the reCAPTCHA

✓ Não sou um robô

reCAPTCHA
Privacidade - Termos

Submit

ADD A PATIENT



Add patient

Search by ID

Worklists ▾

Local investigator user

Add a patient at Hospital de Clínicas de Porto Alegre:

Please note the ID of - BR06-903724

Age years

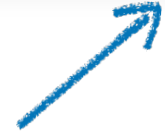
Sex ☒ Female ☐ Male

Ethnicity ☐ Afro-descendant ☒ white ☐ indigenous ☐ other ☐ unknown

Current smoker? ☐ Yes ☒ No

Is the procedure a Caesarean section? ☐ Yes ☒ No

Submit



**Local investigator will login in
and add a new patient**

ADD A PATIENT

You have successfully added a patient.

Please note down their trial ID (BR02-298742), you should have received an email with this information.

Centre: Hospital de Clínicas de Porto Alegre

LASOS ID: BR02-298742

Core data

Co-morbid disease

Surgery

Outcome after surgery

Sign record

Audit trail

Chronic co-morbid disease 

- ☐ None of the below
- ☐ Coronary artery disease
- ☐ Heart failure
- ☐ Diabetes mellitus
- ☐ Cirrhosis
- ☐ Metastatic cancer
- ☐ Hypertension
- ☐ Stroke
- ☐ Chronic Obstructive Pulmonary Disease/Asthma
- ☐ HIV/AIDS
- ☐ Chronic renal disease
- ☐ Active tuberculosis
- ☐ Other
- ☐ SARS-CoV-2 infection in last 6 weeks?

***You need to fill all the fields**

ADD A PATIENT

Centre: Hospital de Clínicas de Porto Alegre

LASOS ID: BR02-298742

Core data

Co-morbid disease

Surgery

Outcome after surgery

Sign record

Audit trail

Anaesthesia induction date  / / (dd/mm/yyyy - enter month in numerals)

Anaesthesia induction time  : (hh:mm)

Anaesthetic technique  ☐ General
☐ Spinal
☐ Epidural
☐ Sedation
☐ Local/Regional

Surgical procedure category  

Urgency of surgery  ☐ Elective ☐ Urgent ☐ Emergency

WHO surgical safety checklist before incision?  ☐ Yes ☐ No

Severity of surgery  ☐ Minor ☐ Intermediate ☐ Major

Laparoscopic surgery  ☐ Yes ☐ No

ADD A PATIENT

Centre: Hospital de Clínicas de Porto Alegre

LASOS ID: BR02-298742

Core data

Co-morbid disease

Surgery

Outcome after surgery

Sign record

Audit trail

Please review the complication definition list found [here](#) when completing this section.

Here you will find a link for the complications definition

Infection

Superficial surgical site  ☐ Mild ☐ Moderate ☐ Severe ☐ None

Deep surgical site  ☐ Mild ☐ Moderate ☐ Severe ☐ None

Body cavity  ☐ Mild ☐ Moderate ☐ Severe ☐ None

Pneumonia  ☐ Mild ☐ Moderate ☐ Severe ☐ None

Urinary tract  ☐ Mild ☐ Moderate ☐ Severe ☐ None


Bloodstream  ☐ Mild ☐ Moderate ☐ Severe ☐ None

Cardiovascular

Myocardial infarction  ☐ Mild ☐ Moderate ☐ Severe ☐ None


ADD A FLAG

You can add a flag if mandatory data is missing, or outside allowed ranges

 **LASOS** Add patient Search by ID Worklists ▾

Centre: Hospital de Clínicas de Porto Alegre LASOS ID: BR02-640763

Core data Co-morbid disease Surgery Outcome after surgery Sign record Audit trail

Chronic co-morbid disease 

Add a data flag


What flag would you like to add to Chronic co-morbid disease ?

- ☐ Data point missing
- ☐ Data not accepted by CRF (put data in box below)
- ☐ Other problem (please complete box below)

- ☐ None of the below
- ☐ Coronary artery disease
- ☐ Heart failure
- ☐ Diabetes mellitus
- ☐ Cirrhosis
- ☐ Metastatic cancer
- ☐ Hypertension
- ☐ Stroke
- ☐ Chronic Obstructive Pulmonary Disease/Asthma
- ☐ HIV/AIDS
- ☐ Chronic renal disease
- ☐ Active tuberculosis
- ☐ Other
- ☐ SARS-CoV-2 infection in last 6 weeks?

MANAGE CRFs

***You can enter new data or correct any information in each CRF going to the worklist - Manage local CRFs**


 LASOS

Add patient

Search by ID

Worklists ▾

Manage local CRFs

 Bianca Stefani ▾

All CRFs entered by your site

Click on any heading to sort by that field.

10 ▾ records per page

Search:

LASOS ID ▴ ▾	Centre ▴ ▾	Date Entered ▴ ▾	Flagged? ▴ ▾	Completed? ▴ ▾	Signed? ▴ ▾	Action ▴ ▾
BR06-903724	Hospital de Clínicas de Porto Alegre	2022-05-07	No	Yes	No	<div><div><input checked="" type="radio"/> No action</div><div><input type="radio"/> Enter data</div></div>

Showing 1 to 1 of 1 entries

Select


← Previous

1

Next →

MANAGE CRFs

Local investigator will mark the record as complete when all information regarding following period are provided

 LASOS [Add patient](#) [Search by ID](#) [Worklists](#) ▼

Centre: Hospital de Clínicas de Porto Alegre **LASOS ID:** BR02-640763

[Core data](#) [Co-morbid disease](#) [Surgery](#) [Outcome after surgery](#) [Sign record](#) [Audit trail](#)

Don't forget to write the LASOS ID on your paper case record form. You may need to come back and check your data.

The LASOS ID for this record is BR02-640763

The following pages are incomplete -

- Surgery
- Outcome after surgery

If required add text in here to explain any omissions or errors

Mark record as complete? ☐ Yes ☐ No

[Submit](#)



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