
RESAR

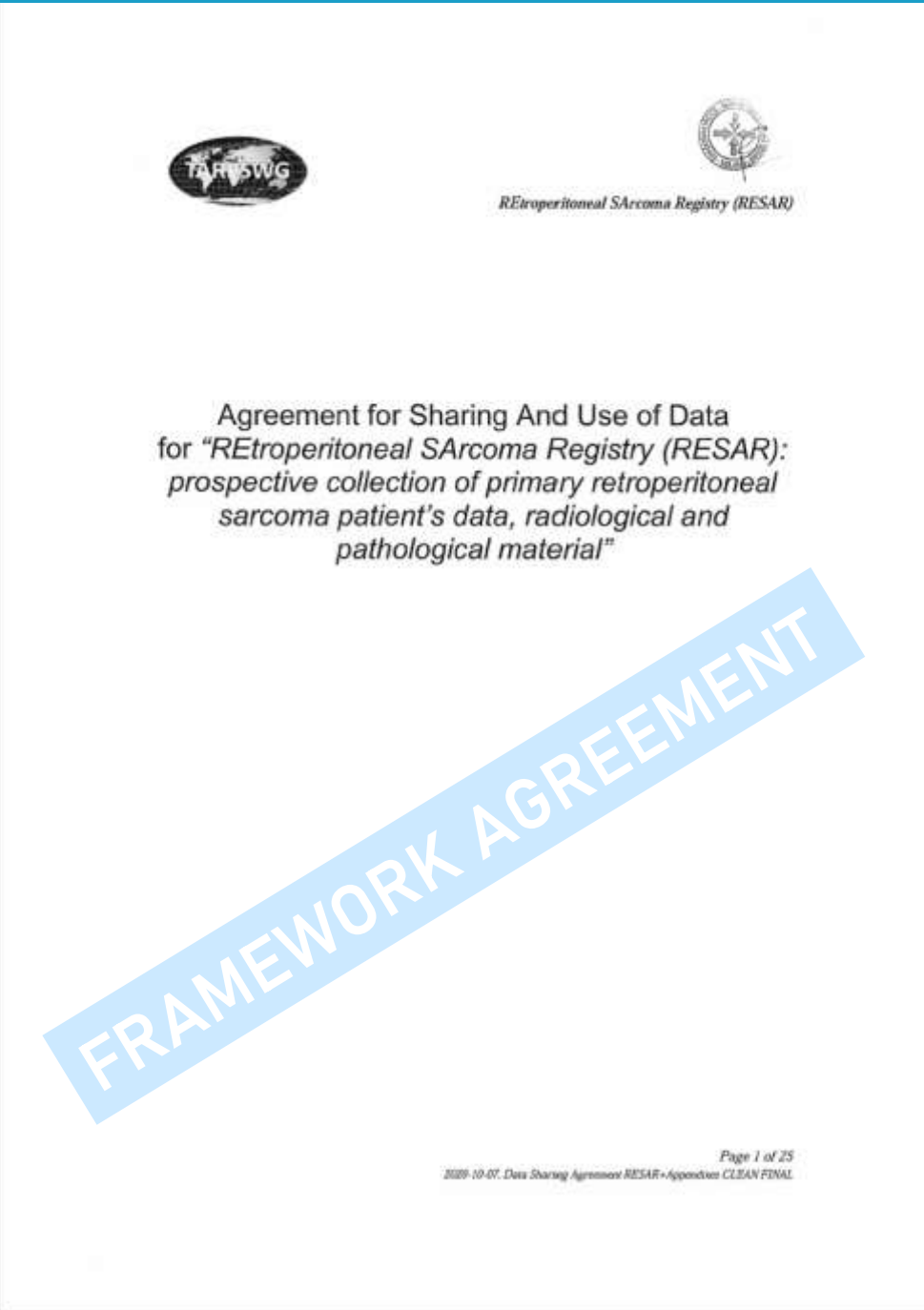
Framework Agreement Data Transfer Agreement Centralization Process

Semiannual Meeting November 2021



“RESAR Vocabulary”

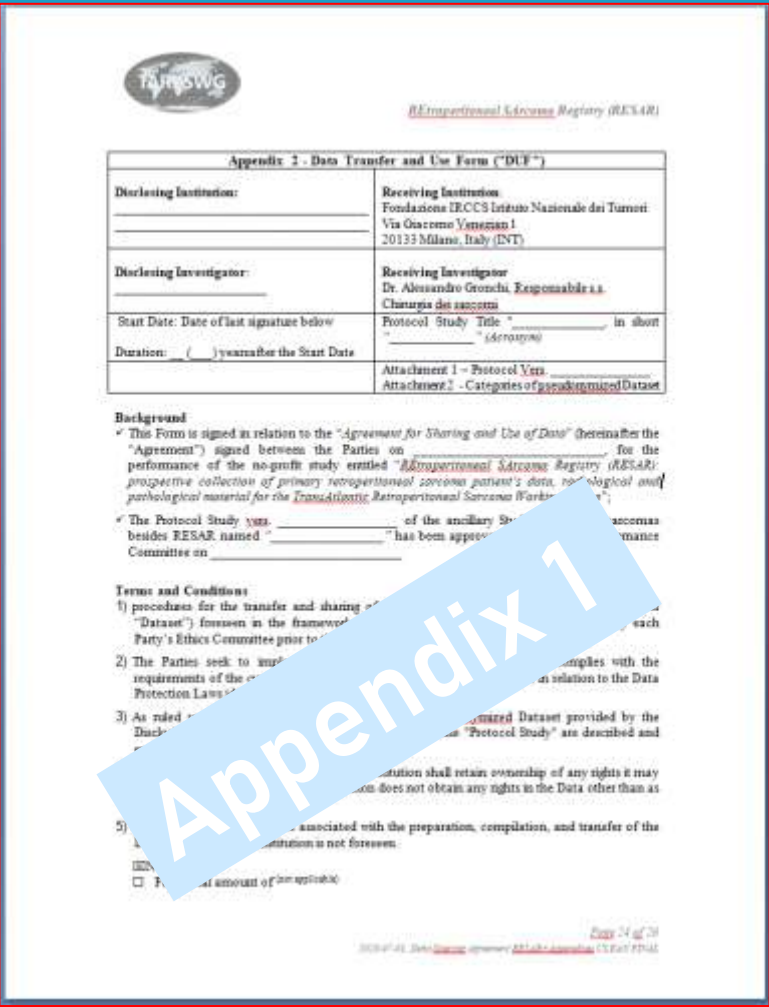
	AKA	Description	Note
Study	Project	A single analysis run within RESAR (usually a subgroup analysis)	Example: Complexity Score, BISARC, etc.
Framework Agreement		Data transfer Agreement between INT and RESAR sites	May be used as legal backbone for other TARPSWG studies (i.e. Pelvisarc
Accession Form	Appendix 1	To be signed by other sites to join the Framework Agreement	
DUF	Appendix 2	Data Usage Form to regulate single studies within the Framework Agreement	For every single study a new DUF need to be signed
RESAR Platform	EXTRA	Online data entry website for centralization of RESAR	Work in progress



Signed October 2020

- INT
- BWH
- JHU
- Ottawa
- Columbus
- PeterMac
- QEH
- IEO

NEW SITES after March 2021:



- Toronto
- Humanitas
- IOV
- Roswell Park
- Fox Chase
- Dukes
- Leuven

Signed in the context of *Complexity Score* Project and *Pelvisarc* project

NEXT ROUND FROM JANUARY 2022:

RESAntiPath

22 centers

Appendix 2

TARPSWG – R2006

Global PoC

29 centers

Appendix 2

TARPSWG – R2005

Benchmarks

24 centers

Appendix 2

TARPSWG – R1906

BISARC

21 centers

Appendix 2

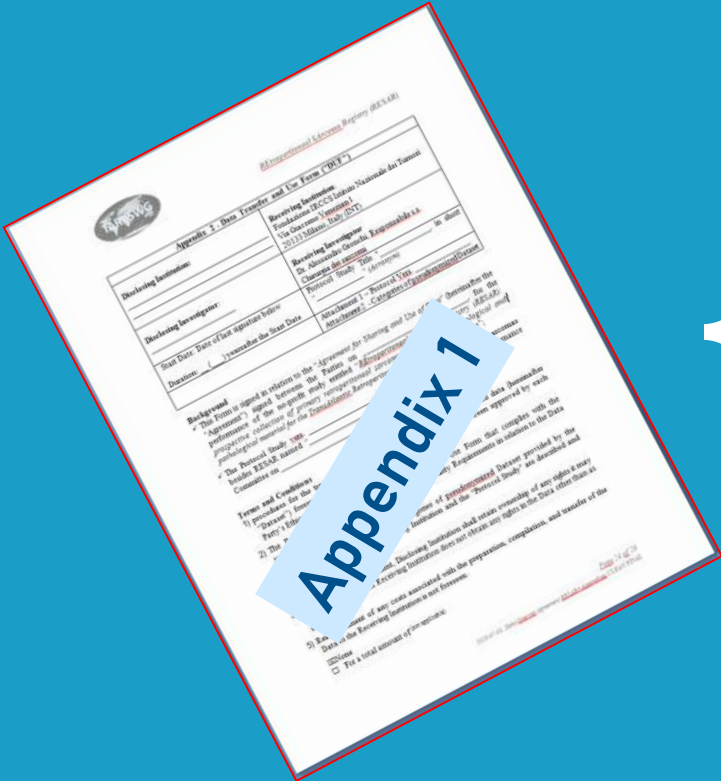
TARPSWG – R1905

NeoAdj Treatment

19 centers

Appendix 2

TARPSWG – R2007



Also need to join Framework Agreement at the same time

Institution	City
Netherlands Cancer Institute	Amsterdam
Winship Cancer Institute, Emory University	Atlanta
Hospital San Pau	Barcelona
Peking University International Hospital	Beijing
Candiolo Cancer Institute	Candiolo
Mayo Clinic	Jacksonville
Leiden University Medical Center	Leiden
Institute of Oncology Ljubljana	Ljubljana
Royal Marsden Hospital	London
University of Southern California (USC)	Los Angeles
Mannheim University Medical Center	Mannheim
McGill University	Montreal
Ludwig Maximilian University	Munich
IOV	Padova
Institut Curie	Paris
Campus Biomedico	Roma
Humanitas	Rozzano
Saitama Medical Center, Jichi Medical University	Saitama
UC San Diego	San Diego
Samsung Medical Center	Seoul
Royal Prince Alfred Hospital	Sydney
Moffitt Cancer Center	Tampa
Tel-Aviv Sourasky Medical Center	Tel-Aviv
National Cancer Center Tokyo	Tokyo
Maria Sklodowska-Curie	Warsaw

DATA TRANSFER AGREEMENT CONTRACT PROCESS

EXTRA

Marco Fiore
User: administrator

Operation

Administration tools

Notifications

Search

Q

Welcome Marco Fiore

Logout

Homepage

View existing patients

The list of your patients

Go to page

Insert new patient

Fill the fields to insert the profile

Go to page

Import CSV

Select file and press Upload button

Go to page

Export data

Page to download csv of patients

Go to page

Functionality for the researcher

Lorem ipsum dolor sit amet

Go to page

Rules

This is the list of the rules for validation

Go to page

Sites

The list of your sites

Go to page

Users

This is the list of the users

Go to page

Selects

This is the list of the form fields

Go to page

Logs

Fill the fields to insert the logs

Go to page

Studies

Lorem ipsum dolor sit amet

Go to page

Messages

Go to page

Alarms

Go to page

Each center can:
-VIEW
-EDIT
-DOWNLOAD
exclusively its own patients

Istituto Nazionale Tumori - Home

page.html

Castor EDCIl mio Drive - Googl...PublonsReviewer CreditsiMedidataElenco di lettura

Search

Welcome Marco FioreLogout

OperationAdministration toolsNotifications

Viewing patients

The list of your patients

Go to page

Insert new patient

Fill the fields to insert the profile

Go to page

Import CSV

Select file and press Upload button

Go to page

Export data

Page to download csv of patients

Go to page

Functionality for the researcher

Lorem ipsum dolor sit amet

Go to page

Rules

This is the list of the rules for validation

Go to page

Sites

The list of your sites

Go to page

Users

This is the list of the users

Go to page

Selects

This is the list of the form fields

Go to page

Logs

Fill the fields to insert the logs

Go to page

Studies

Lorem ipsum dolor sit amet

Go to page

Messages

Go to page

Alarms

Go to page

Each site may have multiple login
credential:
-Local PI
-- Local Co-PI
-Data Manager

Istituto Nazionale Tumori - Home x +

← → ↺ manage.html 🔍 ☆ 🌐 ⋮

Castor EDC Il mio Drive - Googl... P Publons CR Reviewer Credits iMedidata » | 📄 Elenco di lettura

🔔 | Welcome **Marco Fiore** | Logout

Search 🔍

Homepage

Lorem ipsum dolor sit amet

View existing patients

The list of your patients

[Go to page](#)

Insert new patient

Fill the fields to insert the profile

[Go to page](#)

Import CSV

Select file and press Upload button

[Go to page](#)

Export data

Download csv of patients

[Go to page](#)

Functionality for the researcher

Lorem ipsum dolor sit amet

[Go to page](#)

Rules

This is the list of the rules for validation

[Go to page](#)

Sites

The list of your sites

[Go to page](#)

Users

This is the list of the users

[Go to page](#)

Selects

This is the list of the form fields

[Go to page](#)

Logs

Fill the fields to insert the logs

[Go to page](#)

Studies

Lorem ipsum dolor sit amet

[Go to page](#)

Messages

[Go to page](#)

Alarms

[Go to page](#)

EXTRA

Marco Fiore
User: administrator

Operation

Administration tools

Notifications

Search

Q

Marco Fiore | Logout

Homepage

Lorem ipsum dolor sit amet

View existing patients

The list of your patients

Go to page

Insert new patient

Fill the fields to insert the profile

Go to page

Export data

Page to download csv of patients

Go to page

Functionality for the researcher

Lorem ipsum dolor sit amet

Go to page

Sites

The list of your sites

Go to page

Users

This is the list of the user

Go to page

Selects

This is the list of the form fields

Go to page

Logs

Fill the fields to insert the logs

Go to page

Studies

Lorem ipsum dolor sit amet

Go to page

Messages

Go to page

Alarms

Go to page

Existing studies and new studies will be managed within the centralized database:


- Study PI
- Study Co-PI

will have privileges to access data for all patients relevant to the analysis

Istituto Nazionale Tumori - Home

Non sicuro | stage.int.bbsitalia.com/homepage.html

App2020 CTOS Virtual...Lista HUBACS Clinical Congre...Castor EDCIl mio Drive - Googl...PublonsReviewer CreditsiMedidataElenco di lettura



Search

Welcome Marco Fiore | Logout

Marco Fiore
User: administrator

Operation

Administration tools

Notifications

Homepage

Lorem ipsum dolor sit amet

View existing patients

The list of your patients

Go to page

Insert new patient

Fill the fields to insert the profile

Go to page

Import CSV

Select file and press Upload button

Go to page

Export data

Page to download csv of patients

Go to page

Functionality for the researcher

Lorem ipsum dolor sit amet

Go to page

Sites

The list of your sites

Go to page

Users

This is the list of the users

Go to page

Logs

Fill the fields to insert the logs

Go to page

Studies

Lorem ipsum dolor sit amet

Go to page

Messages

Go to page

Alarms

Go to page

It will be possible to adapt / improve dataset or fields if required by a specific study

A tool to randomize patients in prospective studies will also be provided

Istituto Nazionale Tumori - Home

+

Non sicuro | stage.int.bbsitalia.com/homepage.html

App2020 CTOS Virtual...Lista HUBACS Clinical Congre...Castor EDCIl mio Drive - Googl...PublonsReviewer CreditsiMedidataElenco di lettura

EXTRA

Marco Fiore
User: administrator

Operation

Administration tools

Notifications

Search

Q

Marco Fiore | Logout

Homepage

Lorem ipsum dolor sit amet

View existing patients

The list of your patients

Go to page

Insert new patient

Fill the fields to insert the profile

Go to page

Export data

Page to download csv of patients

Go to page

Functionality for the researcher

Lorem ipsum dolor sit amet

Go to page

Sites

The list of your sites

Go to page

Users

This is the list of the users

Go to page

Logs

Fill the fields to insert the logs

Go to page

Studies

Lorem ipsum dolor sit amet

Go to page

Selects

This is the list of the form fields

Go to page

Messages

Go to page


Alarms

Go to page

Data Quality Assurance will be assured by an Website Administrator (RESAR Data Manager) that will check and query centers whenever applicable



Search

 | Welcome **Marco Fiore** | [Logout](#)

Marco Fiore
User: administrator

Operation ▼

[View existing patients](#)

Insert new patient

Import CSV

Export data

Functionality for the researcher

Administration tools ▾

Notifications ▼

Patients List

Patient Demographics

The list of your patients

Search

[illegible]

EXTRA

Marco Fiore
User: administrator

Operation ▾

View existing patients

Insert new patient

Import CSV

Export data

Functionality for the researcher

Administration tools ▾

Notifications ▾

Search

Q

Welcome **Marco Fiore**

Logout

Patient profile #ornguy

Back to Patients List

The details of patient profile

Administration function

DOWNLOAD

EDIT

UNFREEZE

DEMOGRAPHICS ▾		
IMAGING ▾		<div></div>
SURGICAL ▾		<div></div>
MEDICAL ONCOLOGY ▾		<div>Create new</div>
RADIATION ONCOLOGY ▾		<div>Create new</div>
PATHOLOGY ▾		<div>Create new</div>
RECURRENCE ▾	Nr. 0	<div>Create new</div>
VITAL STATUS ▾	Nr. 1	<div>Create new</div>

Istituto Nazionale Tumori - Patier

Non sicuro

stage.int.bbsitalia.com/profile.html?IDExtras=618500e5d3c02&modify=

🔍

☆

🌐

⋮

App

2020 CTOS Virtual...

Lista HUB

ACS Clinical Congre...

Castor EDC

Il mio Drive - Googl...

Publons

Reviewer Credits

iMedidata

»

Elenco di lettura

Import CSV

Export data

Functionality for the researcher

Administration tools

Notifications

DEMOGRAPHICS

IMAGING

SURGICAL

Preoperative medical conditions

Height

Weight

(cm)

Kg

CO-MORBIDITY

Hypertension

Yes

No

Diabetes mellitus

Yes

No

COPD

Yes

No

Coronary artery disease

Yes

No

Chronic renal disease

Yes

No

If other, specify

free text (50 max.)

LAST BLOOD TESTS BEFORE SURGERY

Hemoglobin

observed value

WBC

Top

RESAR PLATFORM – “EXTRA”

CENTRALIZED DATABASE

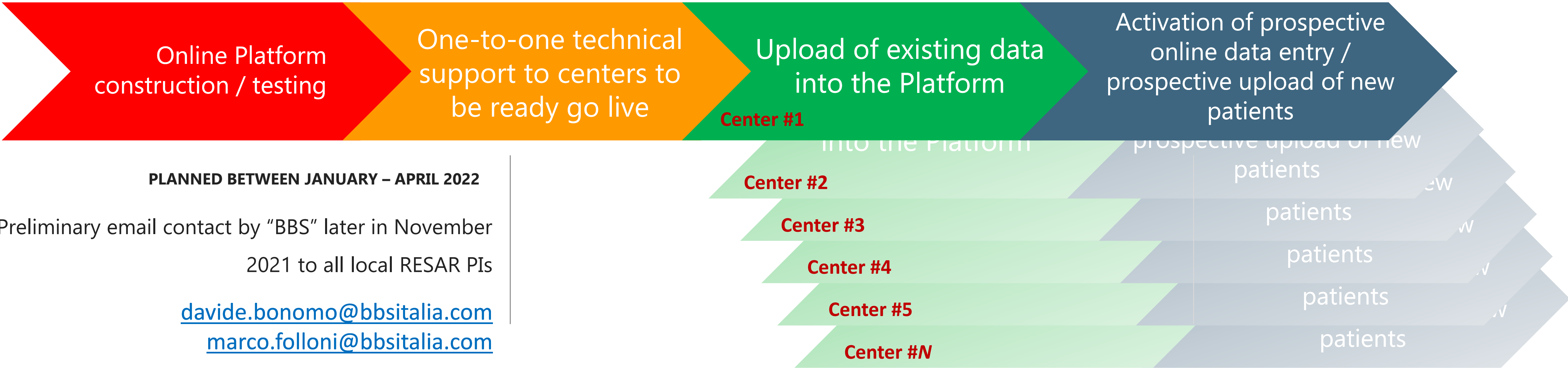


PRESENTLY ONGOING

Provided by BBS Italia
with support by RESAR Data
Manager (Dr. Martina Ronchi)

PLANNED BETWEEN SEPTEMBER – DECEMBER 2022

Activation of RESAR centers within
centralized platform EXTRA



PLANNED BETWEEN JANUARY – APRIL 2022

Preliminary email contact by “BBS” later in November
2021 to all local RESAR PIs
davide.bonomo@bbsitalia.com
marco.folloni@bbsitalia.com

RESAR PLATFORM – “EXTRA”

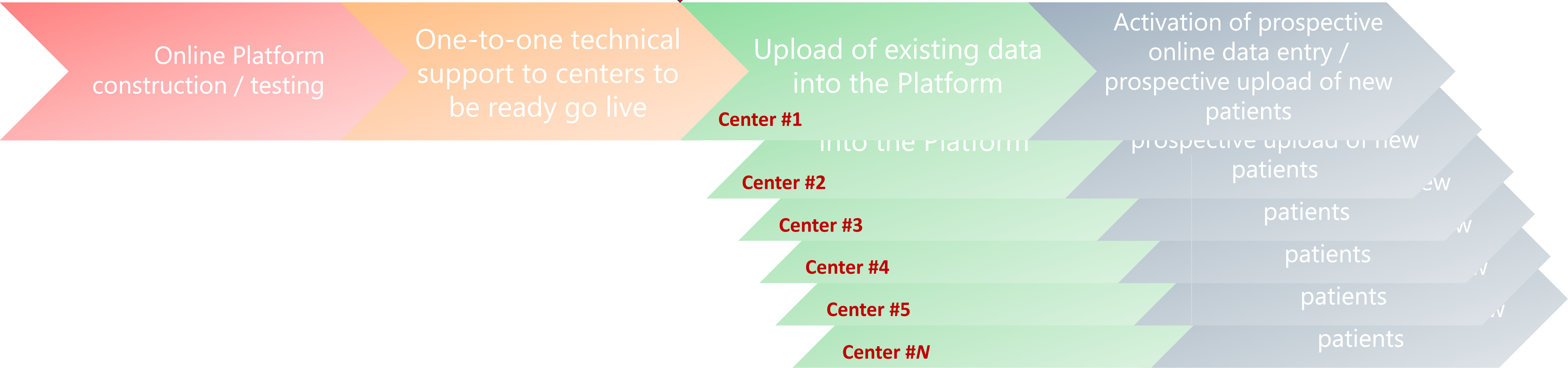


PLANNED STARTING JANUARY 2022
Comply DTA to the centralized database structure
by INT Legal Office

CENTRALIZED DATABASE



PLANNED JUNE – DECEMBER 2022
Executed / Signed Updated Framework Agreement with INT



How to be prepared to CENTRALIZATION PROCESS

1. Local **IRB Approval** of RESAR is MANDATORY (be ready to transmit)
2. For those center who did not sign **Framework Agreement**:
 - Please support us in contact with your **Legal Office** to expedite procedures
 - Push Offices to sign documents!
 - Framework Agreement **will not be negotiable** (international laws; >40 institutions)
3. Any delay in contract procedure will affect the whole database project

PLEASE CONTACT marco.fiore@istitutotumori.mi.it and martina.ronchi@istitutotumori.m.it
TO BE PREPARED

FOR NEW CENTERS: HOW TO JOIN RESAR

OPEN TO ANY TARPSWG CENTER



DECLARATION OF INTEREST

Please contact:

marco.fiore@istitutotumori.mi.it or

tarpswg@gmail.com

FOR DATA TRANSFER AGREEMENT

Contact

marco.fiore@istitutotumori.mi.it

martina.ronchi@istitutotumori.mi.it

Documents: study protocol,
dataset

Local IRB
approval

Join Framework
Agreement

Center Activation

FIND MATERIALS AND
DOWNLOAD HERE:

<https://tarpswg.org/resar-study-documentation/>

Logins for EXTRA
Platform for online data
entry will be released