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# RESAR Update Contracts and IT Centralization

SEMIANNUAL MEETING SSO MARCH 9 2022





# ENROLLED PATIENTS

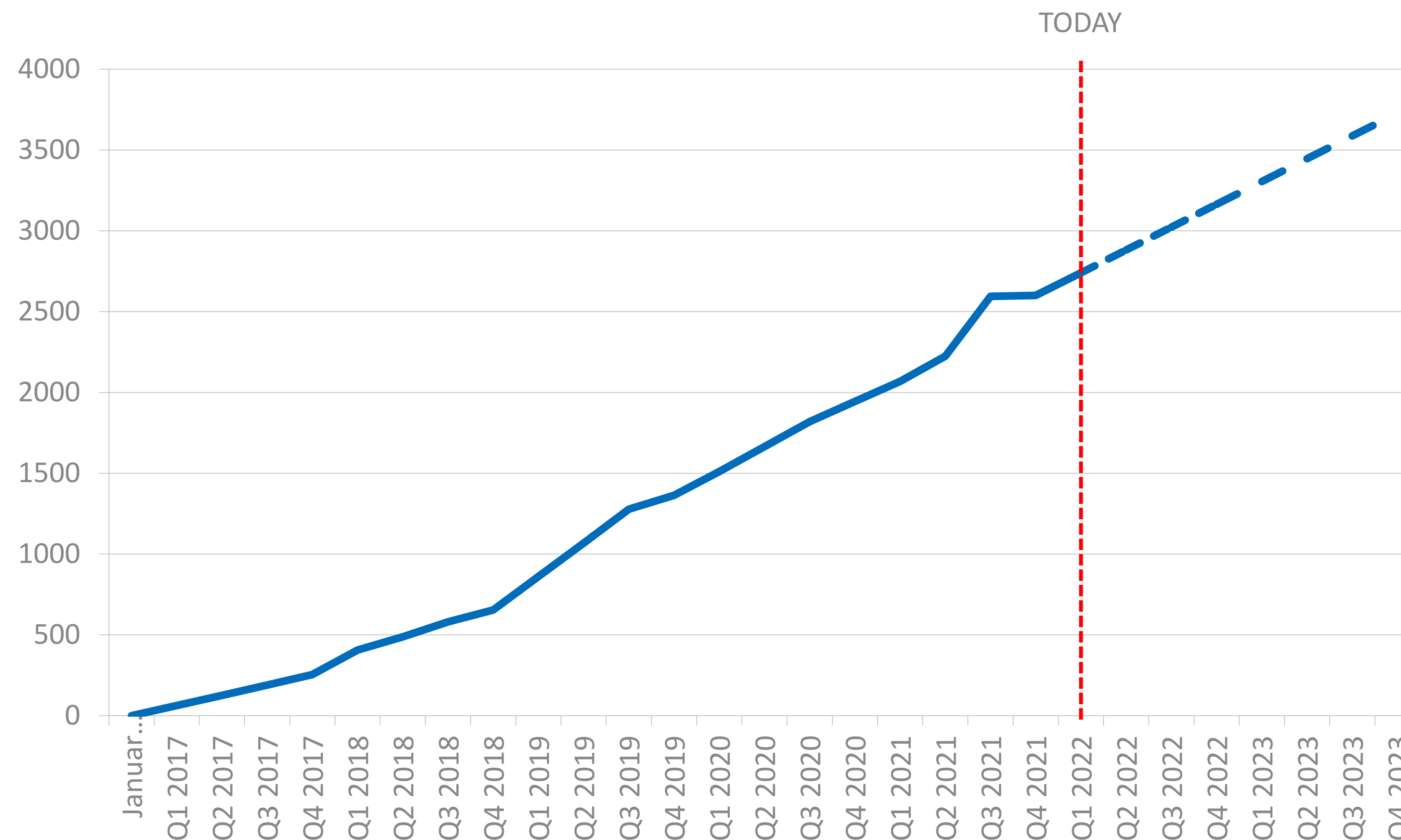
RESAR

2741 patients  
(+196 from Nov 2021)

As of Oct 2021

45 (+0 since Nov 2021)

Centers enrolling



# “RESAR Vocabulary”

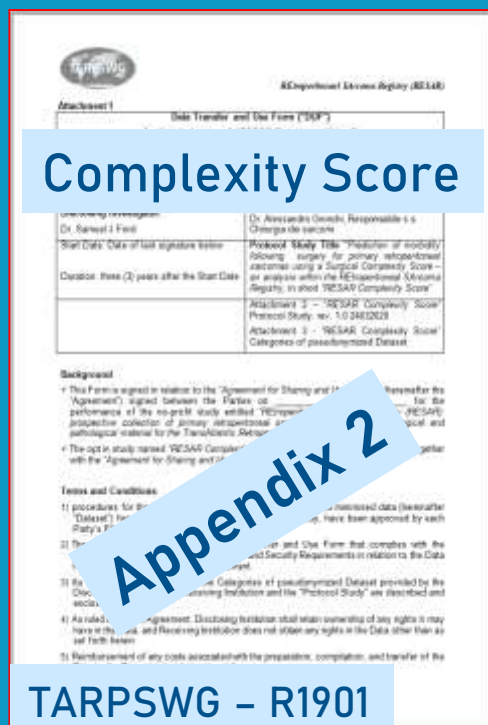
	AKA	Description	Note
<b>Study</b>	Project	A single analysis run within RESAR (usually a subgroup analysis)	Example: Complexity Score, BISARC, etc.
<b>Framework Agreement</b>		Data transfer Agreement between INT and RESAR sites	May be used as legal backbone for other TARPSWG studies (i.e. Pelvisarc
<b>Accession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

# CONTRACTS

TARPSWIG

PLEASE CONTACT [marco.fiore@istitutotumori.mi.it](mailto:marco.fiore@istitutotumori.mi.it) TO BE PREPARED

# TARPSWG-R1901 COMPLEXITY SCORE



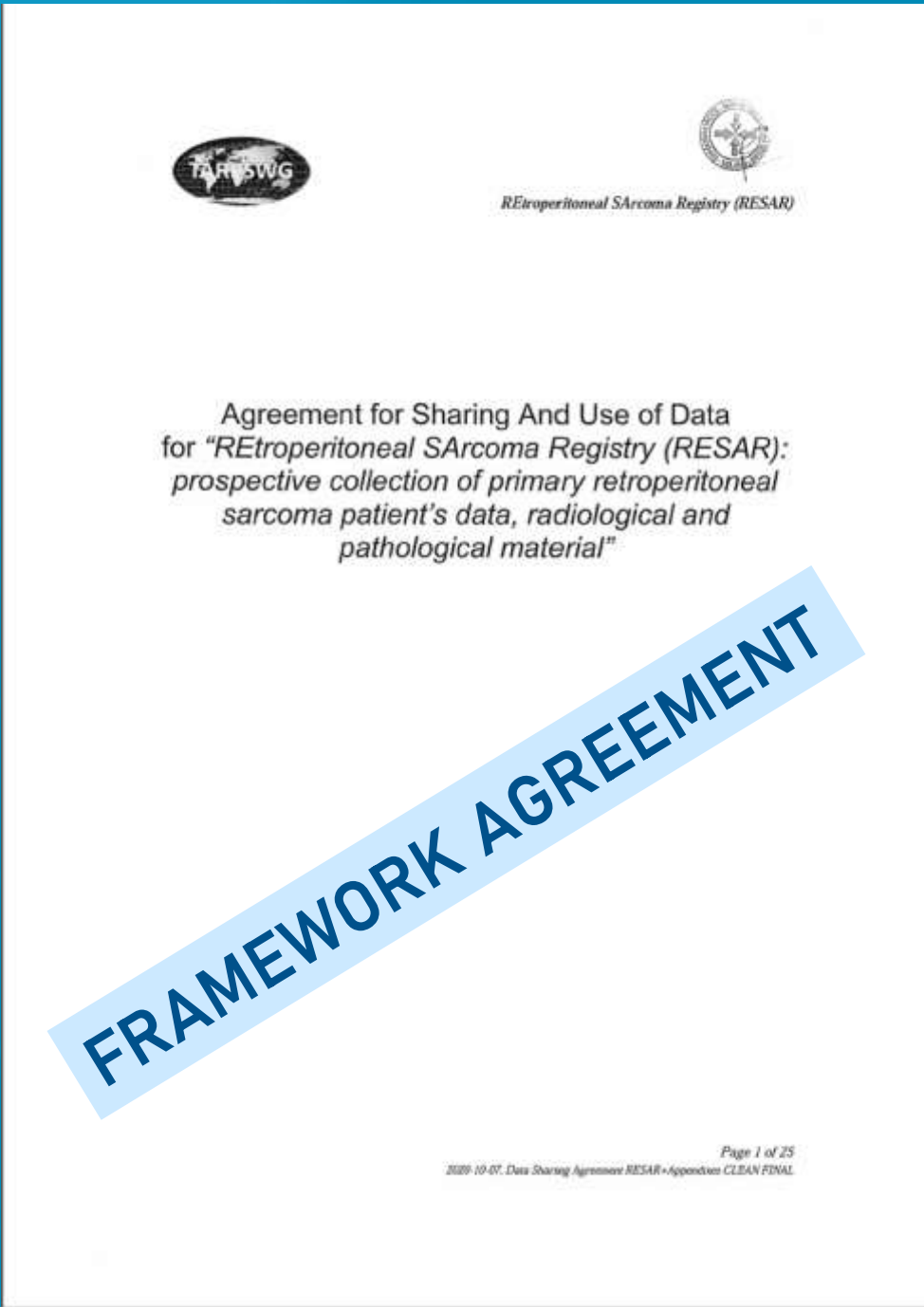
- **Contract for data transfer CLOSED**
- **22 participating centers**
- **1247 patients already collected**  
**(still pending data from Amsterdam for technical issues)**
- **Waiting for final statistical plan by M. Fairweather**
- **Final round of data cleaning: March-May 2022**
- **Deadline: ??**

Netherlands Cancer Institute
Winship Cancer Institute, Emory University
Johns Hopkins University
Hospital Sant Pau
Queen Elizabeth Hospital Birmingham
Institut Bergonié
Brigham and Women’s Hospital/Dana-Farber Cancer Institute
The Ohio State University
Institute of Oncology Ljubljana
Royal Marsden Hospital
Peter MacCallum Cancer Center
European Institute of Oncology
Fondazione IRCCS Istituto Nazionale dei Tumori
Ludwig Maximilian University
The Ottawa Hospital
Veneto Institute of Oncology
Institut Curie
Campus Biomedico
Humanitas Cancer Center
Moffitt Cancer Center
Mount Sinai / Princess Margaret
Maria Sklodowska-Curie Warsaw

## DATA TRANSFER AGREEMENT CONTRACT PROCESS



# CENTERS ALREADY PARTNERS WITHIN FRAMEWORK AGREEMENT



- |          |           |
|----------|-----------|
| INT      | Toronto   |
| BWH      | Fox Chase |
| JHU      | Duke      |
| Ottawa   | Leuven    |
| Columbus |           |
| PeterMac |           |
| QEH      |           |
| IEO      |           |

DATA TRANSFER AGREEMENT CONTRACT PROCESS

PROCESS ONGOING SINCE FEBRUARY 2022

RESAntiPath

22 centers

Appendix 2

TARPSWG – R2006

Global PoC

29 centers

Appendix 2

TARPSWG – R2005

Benchmarks

26 centers

Appendix 2

TARPSWG – R1906

BISARC

22 centers

Appendix 2

TARPSWG – R1905

NeoAdj Treatment

19 centers

Appendix 2

TARPSWG – R2007

Appendix 1

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



# PROCESS ONGOING SINCE FEBRUARY 2022

Attachment 1

RESAntiPath

22 centers

Appendix 2

TARPSWG – R2006

Attachment 1

Global PoC

29 centers

Appendix 2

TARPSWG – R2005

Attachment 1

Benchmarks

24 centers

Appendix 2

TARPSWG – R1906

Attachment 1

BISARC

21 centers

Appendix 2

TARPSWG – R1905

Attachment 1

NeoAdj Treatment

19 centers

Appendix 2

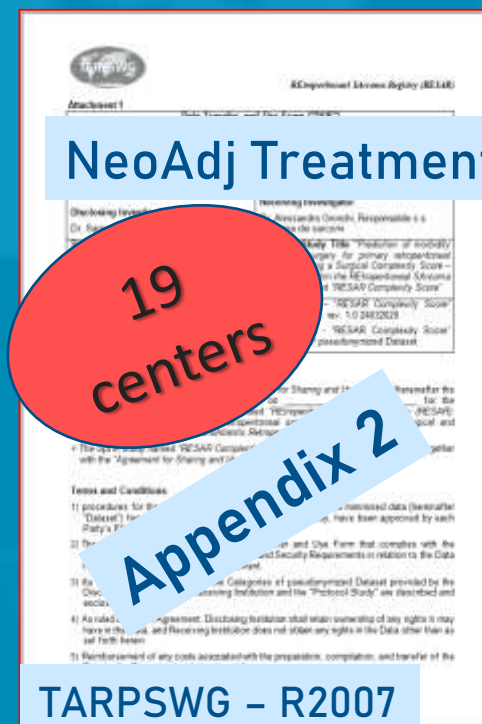
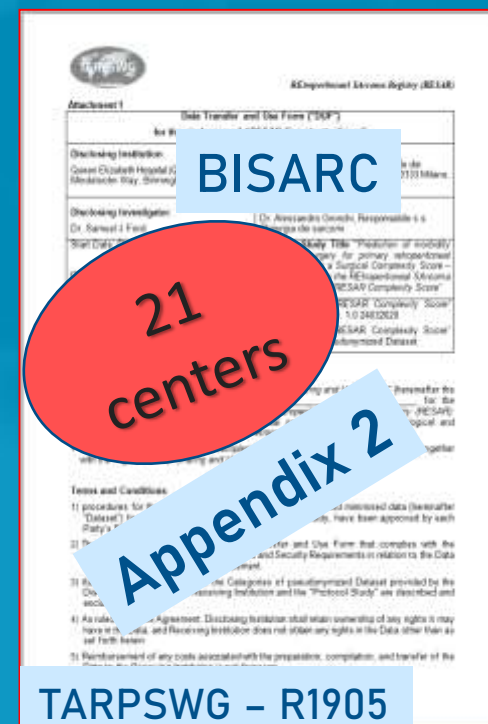
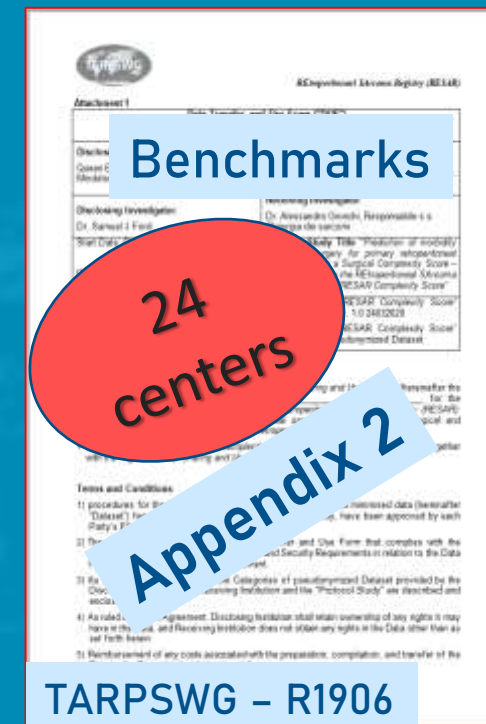
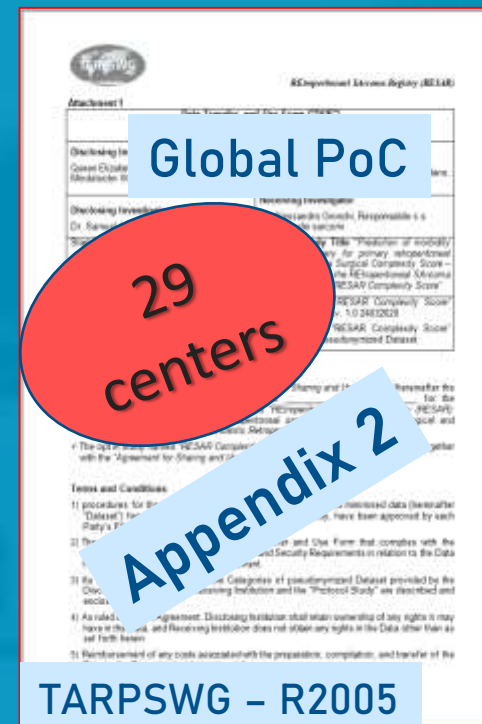
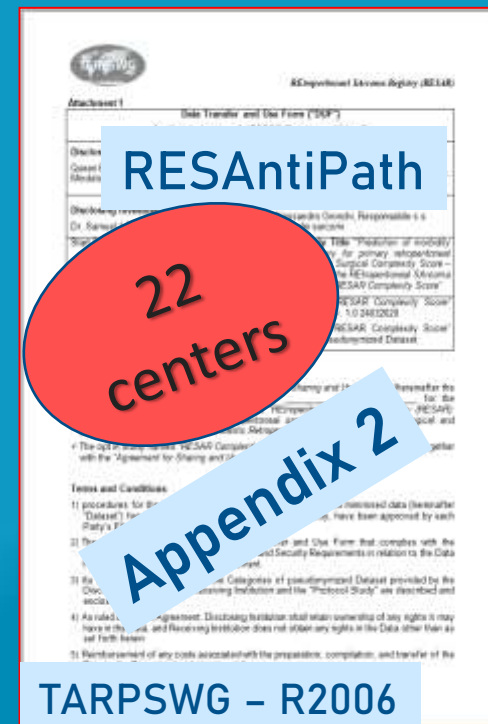
TARPSWG – R2007

## Priority timeline for contract signatures:

- Centers already partners of Framework Agreement
  - Batch of email according to type of study to be joined
- Centers who need to also join the Framework Agreement
  - Batch of email according to type of study to be joined
  - Prioritized according to patient-volume



# PROCESS ONGOING SINCE FEBRUARY 2022



## How does it work:

1. Legal Office of INT ([paola.loro@istitutotumori.mi.it](mailto:paola.loro@istitutotumori.mi.it)) will reach by email:

- Local RESAR Scientific PI
- Local Legal Representative
- Local Contact at your Legal Office

2. Contract should be signed **ELECTRONICALLY** through **Docusign®** facility (5 mins to sign!!)

- Signature of Local RESAR Scientific PI
- Signature of Local Legal Representative
- Signature of RESAR PI Dr. Gronchi
- Signature of INT Legal Representative

DATA TRANSFER AGREEMENT CONTRACT PROCESS



# IT CENTRALIZATION

TARPSWIG

Istituto Nazionale Tumori - Home

Non sicuro

stage.int.bbsitalia.com/homepage.html

App

2020 CTOS Virtual...

Lista HUB

ACS Clinical Congre...

Castor EDC

Il mio Drive - Googl...

Publ...

EXTRA

Search

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

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

RESAR PLATFORM – “EXTRA”

CENTRALIZED DATABASE





# RESAR PLATFORM – “EXTRA” CENTRALIZED DATABASE

PLANNED STARTING May 2022

Comply DTA to the centralized database structure  
by INT Legal Office

UPDATE OF FRAMEWORK  
AGREEMENT INCLUDING  
CENTRALIZATION OF DATA

SIGNATURE OF UPDATED FRAMEWORK AGREEMENT FOR  
CENTERS WHO ARE NOT YET PART OF IT

PLANNED JUNE – DECEMBER 2022

**Executed / Signed Updated Framework  
Agreement with INT**

**VERY IMPORTANT FOR CENTERS WHO  
JOINED RESAR IN 2021 AND FOR NEW  
CENTERS:**

Be in contact with  
[martina.ronchi@istitutotumori.mi.it](mailto:martina.ronchi@istitutotumori.mi.it)  
[daniela.salvatore@istitutotumori.mi.it](mailto:daniela.salvatore@istitutotumori.mi.it)  
for the following:

- Obtain ASAP local IRB approval for RESAR
- Communicate contact info for: local PI, local Legal Representative, local contact at Legal Office

ONLINE PLATFORM  
CONSTRUCTION /  
TESTING

Done!

ONE-TO-ONE TECHNICAL  
SUPPORT TO CENTERS TO BE  
READY GO LIVE

Will be presented  
today

UPLOAD OF EXISTING DATA INTO THE  
PLATFORM

Center #1

Center #2

Center #3

Center #4

Center #5

Center #N

ACTIVATION OF PROSPECTIVE ONLINE  
DATA ENTRY / PROSPECTIVE UPLOAD OF  
NEW PATIENTS

prospective upload of  
new patients

new patients

new patients

new patients

new patients

PLEASE CONTACT [marco.fiore@istitutotumori.mi.it](mailto:marco.fiore@istitutotumori.mi.it) and [martina.ronchi@istitutotumori.m.it](mailto:martina.ronchi@istitutotumori.m.it) / [daniela.salvatore@istitutotumori.mi.it](mailto:daniela.salvatore@istitutotumori.mi.it)  
TO BE PREPARED

# How does it work?

## 1. Upload of existing data from local databases

- From Filemaker export
- From Excel export
- From RedCap export

*Be aware: ongoing studies R1905, R1906, R2005, R2006, R2007 will be managed out of this platform!*

## 2. Prospective data-entry of new data

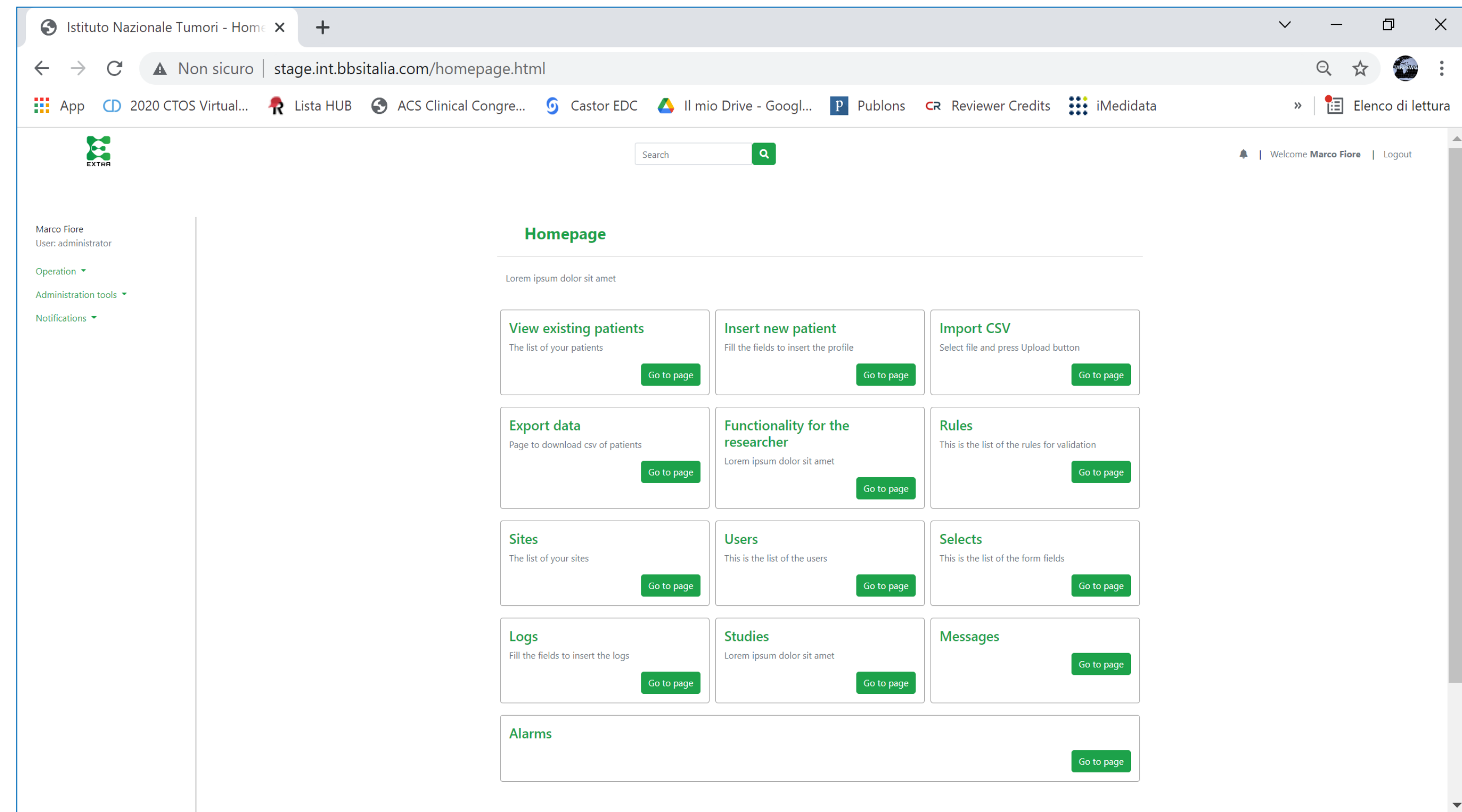
- Directly online
- From local Filemaker export
- From local Excel export

*Be aware: a new modified Excel template will be distributed and aligned with your previous data*

## 3. Each center will be able anytime to locally download its own data

## RESAR PLATFORM – “EXTRA”

### CENTRALIZED DATABASE



### Online dataentry will be the ONLY option for:

- New centers joining RESAR from now on
- Enter data of patients potentially included in future «RCT» within RESAR (to be able to run patient's randomisation)

# FOR NEW CENTERS: HOW TO JOIN RESAR

OPEN TO ANY TARPSWG CENTER



## DECLARATION OF INTEREST

Please contact:

[marco.fiore@istitutotumori.mi.it](mailto:marco.fiore@istitutotumori.mi.it)

[tarpswg@gmail.com](mailto:tarpswg@gmail.com)

## FOR DATA TRANSFER AGREEMENT

Contact

[marco.fiore@istitutotumori.mi.it](mailto:marco.fiore@istitutotumori.mi.it)

[martina.ronchi@istitutotumori.mi.it](mailto:martina.ronchi@istitutotumori.mi.it)

[daniela.salvatore@istitutotumori.mi.it](mailto:daniela.salvatore@istitutotumori.mi.it)

DOCUMENTS: STUDY  
PROTOCOL, DATASET

LOCAL IRB  
APPROVAL

JOIN FRAMEWORK  
AGREEMENT

CENTER  
ACTIVATION

FIND MATERIALS AND DOWNLOAD HERE:

[tarpswg.org/resar-study-documentation](http://tarpswg.org/resar-study-documentation)

LOGINS FOR EXTRA  
PLATFORM FOR ONLINE  
DATA ENTRY WILL BE  
RELEASED