
RESAR Update Contracts and IT Centralization

SEMIANNUAL MEETING SSO MARCH 9 2022





ENROLLED PATIENTS

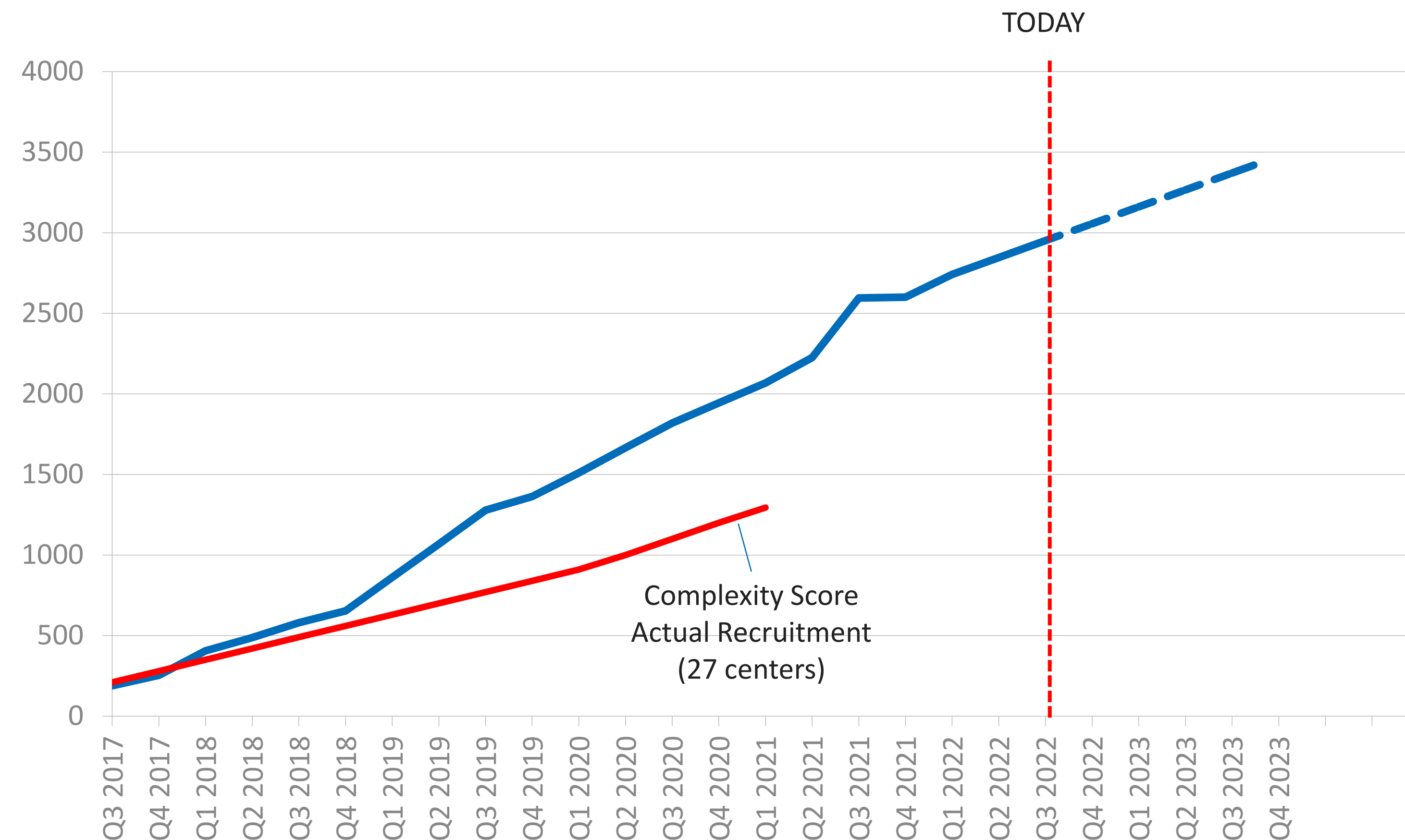
RESAR

2951 patients
(+210 from March 2022)

As of Sept 1st 2022

51 (+6 since Nov 2021)

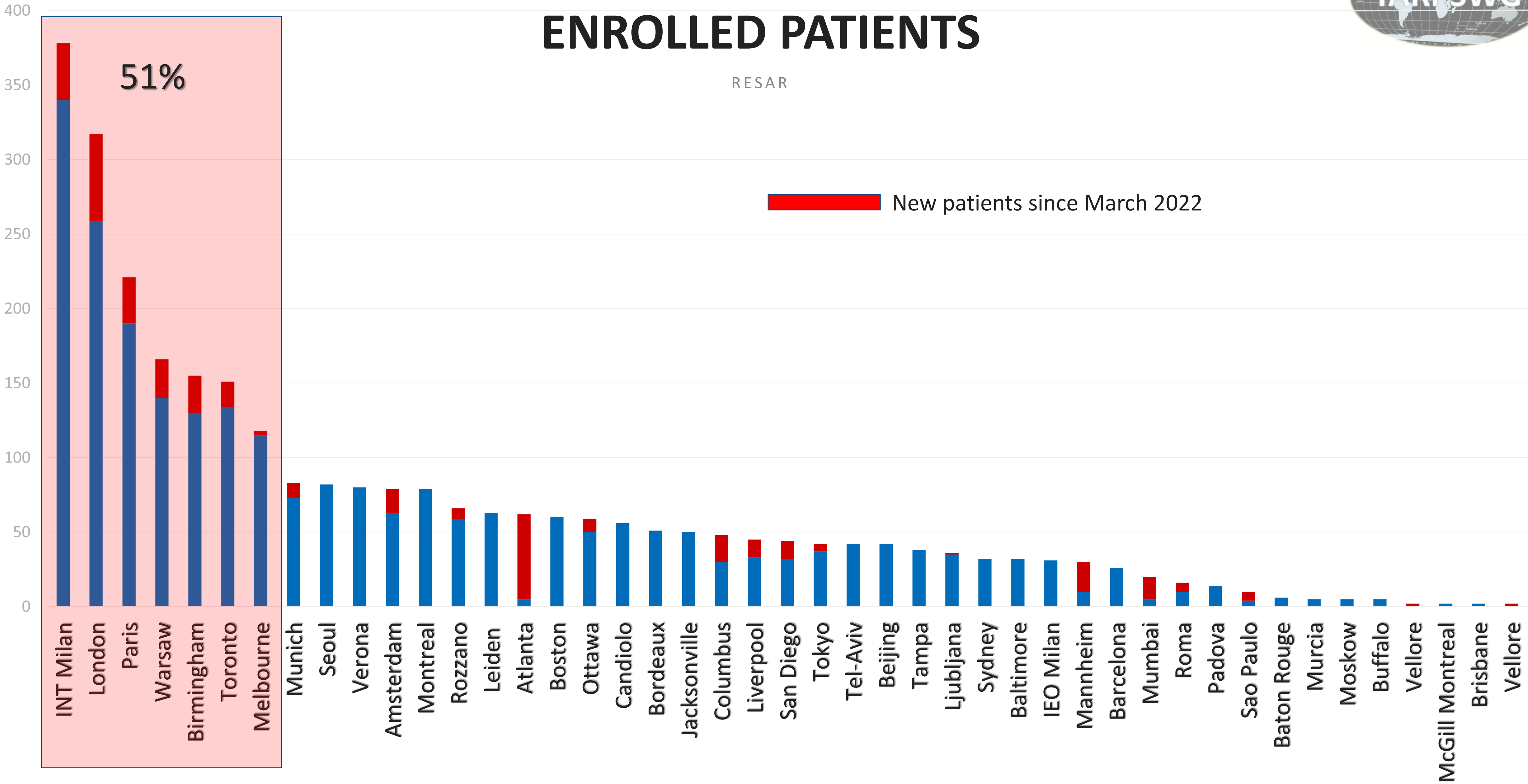
Centers enrolling





ENROLLED PATIENTS

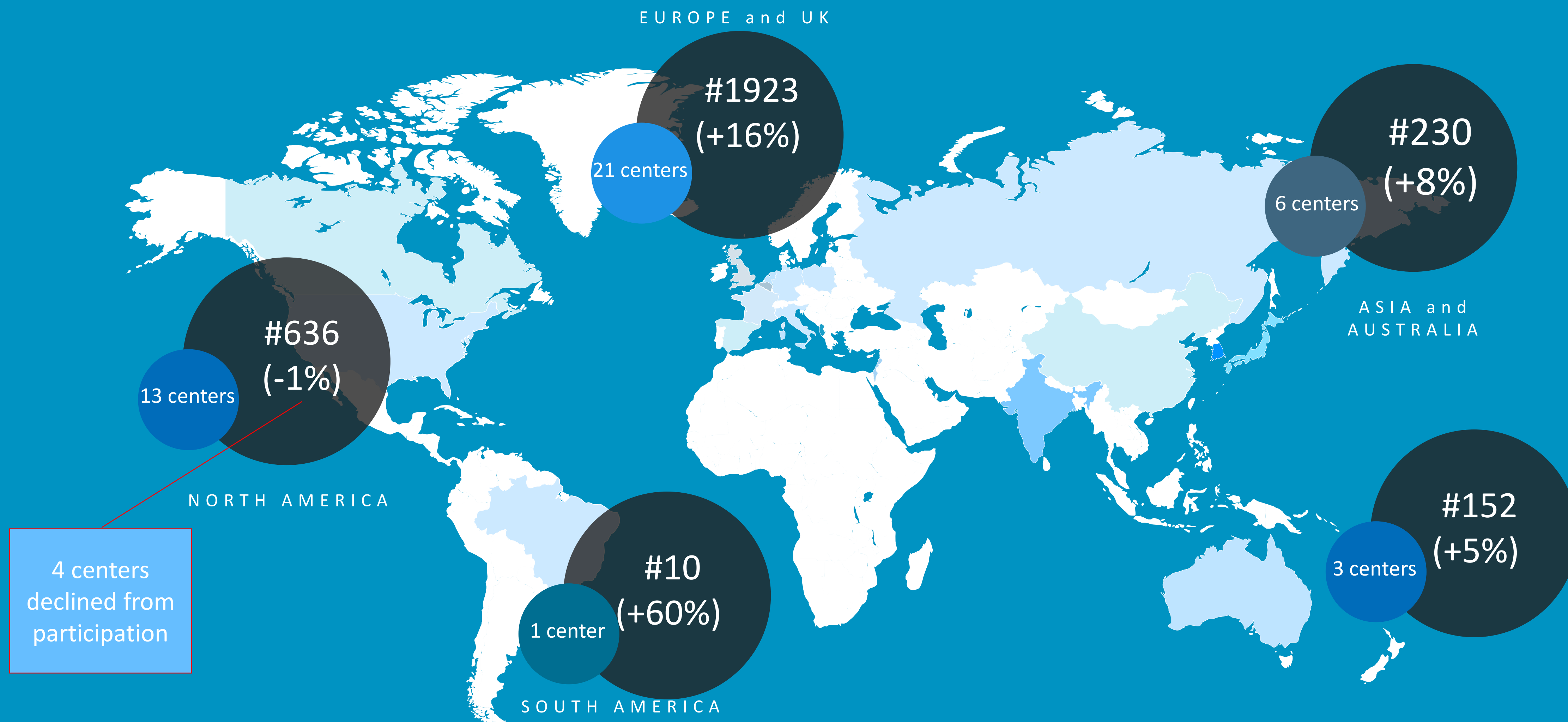
RESAR





ENROLLED PATIENTS

51 Active Sites



CONTRACTS

TARPSWG

PLEASE CONTACT marco.fiore@istitutotumori.mi.it TO BE PREPARED

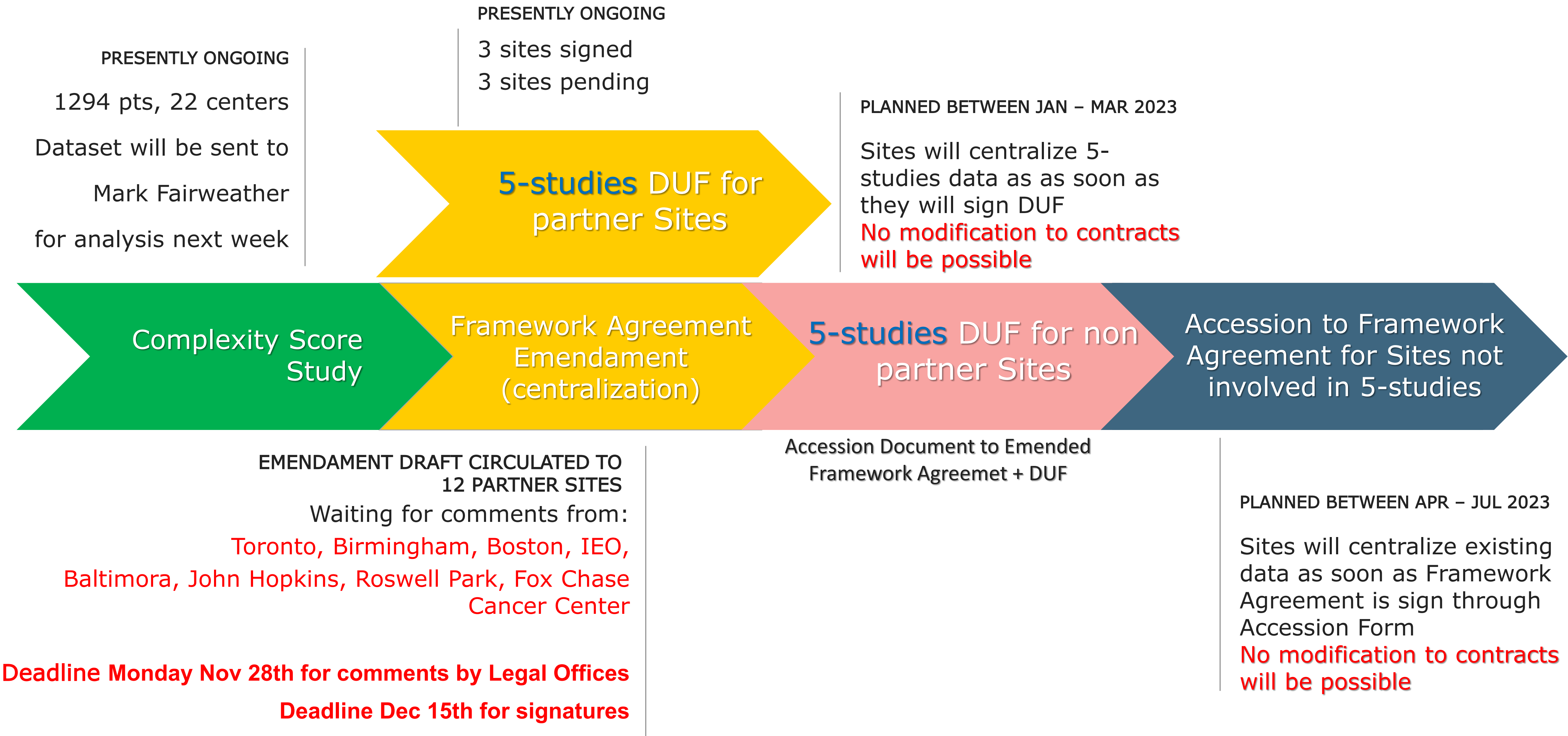
“RESAR Vocabulary”

	AKA	Description	Note
Framework Agreement	DTA	Data transfer Agreement between INT and RESAR sites	Legal backbone for TARPSWG studies. Presently 12 Institutions are partners
Emended Framework Agreement		Will include centralization of data in the online Platform	Presently under consideration of 12 partners, then will be open to other centers
Study	Project	A single analysis run within RESAR (usually a subgroup analysis)	Example: Complexity Score, BISARC, etc.
Five Studies	5 studies	BISARC, Pattern of Care, Benchmarks, Response to Neoadjuvant, ResAntiPath	Regulated out of centralization process; already ongoing; closed to opt in
Accession Form	Appendix 1	To be signed by other sites to join the Emended 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	Presently tested for acquisition of retrospective data; will be used as prospective eCRF

ONGOING CONTRACTS Activities



5-studies: BISARC, Pattern of Care, Response to Neoadjuvant, ResAntiPath, Benchmarks



Status of Contract/Centralization of 44 Active Sites



for more info: Daniela.Salvatore@istitutotumori.mi.it

Alert Legend:

OK - ready

Delay not related to Site

Delay related to Site

Major Issue Pending

Institution	City	Activation Status	Framework Agreement n.1	Framenwork Agreement Process	Centralization Test	DUF 5-studies	PI contact
INT	Milano	Recruiting	✓				
RMH	London	Recruiting					
Institut Curie	Paris	Recruiting					
Maria Sklodowska-Curie	Warsaw	Recruiting					
QEH	Birmingham	Recruiting	✓				
Mount Sinai / Princess Margaret	Toronto	Recruiting	✓				
Peter Mac	Melbourne	Recruiting	✓				
LMU	Munich	Recruiting					
Samsung Medical Center	Seoul	Recruiting					
Ospedale Borgo Roma	Verona	Recruiting					
University of Montreal	Montreal	Recruiting					
NKI	Amsterdam	Recruiting					
Humanitas	Rozzano	Recruiting					
LUMC	Leiden	Recruiting					
Emory	Atlanta	Recruiting					
BWH/DFCI	Boston	Recruiting	✓				
The Ottawa Hospital	Ottawa	Recruiting	✓				
Candiolo Cancer Institute	Candiolo	Recruiting					
Institut Bergonié	Bordeaux	Recruiting					
Mayo Clinic	Jacksonville	Recruiting					
OSU	Columbus	Recruiting	✓				
Liverpool University	Liverpool	Recruiting					

Institution	City	Activation Status	Framework Agreement n.1	Framenwork Agreement Process	Centralization Test	DUF 5-studies	PI contact
UC San Diego	San Diego	Recruiting					
National Cancer Center Hospital	Tokyo	Recruiting					
Tel-Aviv Sourasky	Tel-Aviv	Recruiting					
Peking University	Beijing	Recruiting					
Moffitt	Tampa	Recruiting					
Institute of Oncology Ljubljana	Ljubljana	Recruiting					
Royal Prince Alfred Hospital	Sydney	Recruiting					
Johns Hopkins University	Baltimore	Recruiting	✓				
IEO	Milano	Recruiting	✓				
MUMC	Mannheim	Recruiting					
Hospital Sant Pau	Barcelona	Recruiting					
Tata Memorial	Mumbai	Recruiting					
Campus Biomedico	Roma	Recruiting					
IOV	Padova	Recruiting					
A.C. Camargo Cancer Center	Sao Paulo	Recruiting					
Mary Bird Perkins	Baton Rouge	Recruiting					
Virgen de la Arrixaca	Murcia	Recruiting					
N.N. Blokhin	Moskow	Recruiting					
Roswell Park	Buffalo	Recruiting	✓				
McGill University	Montreal	Recruiting					
Princess Alexandra Hospital	Brisbane	Recruiting					
Christian Medical College	Vellore	Recruiting					

11 Sites being activated

For more info: Daniela.Salvatore@istitutotumori.mi.it



Alert Legend: OK - ready Delay not related to Site Delay related to Site Major Issue Pending

Institution	City	Activation Status	Framework Agreement n.1	Framenwork Agreement Process	Centralization Test	DUF 5-studies	PI contact
IPO	Porto	Approved, ready to recruit					
Saitama Medical Center	Saitama	Approved, ready to recruit					
Sylvester - Univ Miami	Miami	Approved, ready to recruit					
Patel Hospital	Karachi	Approved, ready to recruit					
Instituto de Oncologia Angel Roffo	Buenos Aires	Approved, ready to recruit					
Instituto Nacional de Cancerología	Bogotá	Approved, ready to recruit					
Tallaght Univesity Hospital	Dublin	Submitted to IRB, pending for decision					
Città della Salute e della Scienza	Turin	Submitted to IRB, pending for decision					
Royal Adelaide Hospital	Adelaide	Submitted to IRB, pending for decision					
CRO	Aviano	Submitted to IRB, pending for decision					
Aretaieio University Hospital	Athens	Submitted to IRB, pending for decision					

6 Sites: Ready to recruit
5 Sites: Waiting for Local IRB Approval

31 Sites with Declaration of Interest (no further progress)



PLEASE FOR UPDATES: Marco.Fiore@istitutotumori.mi.it

City	Institution	Country
Ann Arbor, MI	University of Michigan	USA
Auckland	?	New Zealand
Bern	Inselspital	Switzerland
Boston	Massachusetts General Hospital	Massachusetts, USA
Catania	Ospedale Garibaldi	Italy
Coimbra	Instituto Português de Oncologia de Coimbra	Portugal
Copenhagen	Rigshospital	Denmark
Duarte	City of Hope National Medical Center	California, USA
Gent	Ghent University Hospital	Belgium
Göttingen	University Medical Center Göttingen	Germany
Hong Kong	The Chinese University of Hong Kong / Prince of Wales Hospital	Hong Kong
Houston	MD Anderson Cancer Center	Texas, USA
Kansans City	The University of Kansas Health System	USA
Kyiv	National Cancer Institute	Ukraine
Leeds	St James's University Hospital	United Kingdom
Leuven	UZ Leuven	The Netherlands

City	Institution	Country
Maastricht	MUMC Maastricht University Medical Center	The Netherlands
Madrid	Hospital Gregorio Maranon	Spain
Mexico City	Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán	Mexico
Mexico City	Instituto National de Cancerologia	Mexico
Milwaukee	Aurora St. Luke's Medical Center	Wisconsin, USA
Muscat	Sultan Qaboos Comprehensive Cancer Care and Research Al Khoud	Oman
Napoli	Istituto Nazionale Tumori di Napoli - Fondazione Pascale	Italy
New Delhi	All India Institute of Medical Science AIIMS	India
New Haven	Yale New Haven Hospital	USA
Philadelphia	Fox Chase Cancer Center	Pennsylvania, USA
Portland, OR	Oregon Health and Science University	USA
Santiago	Instituto Oncológico Fundación Arturo López Pérez (FALP)	Chile
Sydney	Westmead Hospital	New South Wales, Australia
Taipei	National Taiwan University Hospital	Taiwan
Tel-Aviv	Sheba Medical Centre	Israel

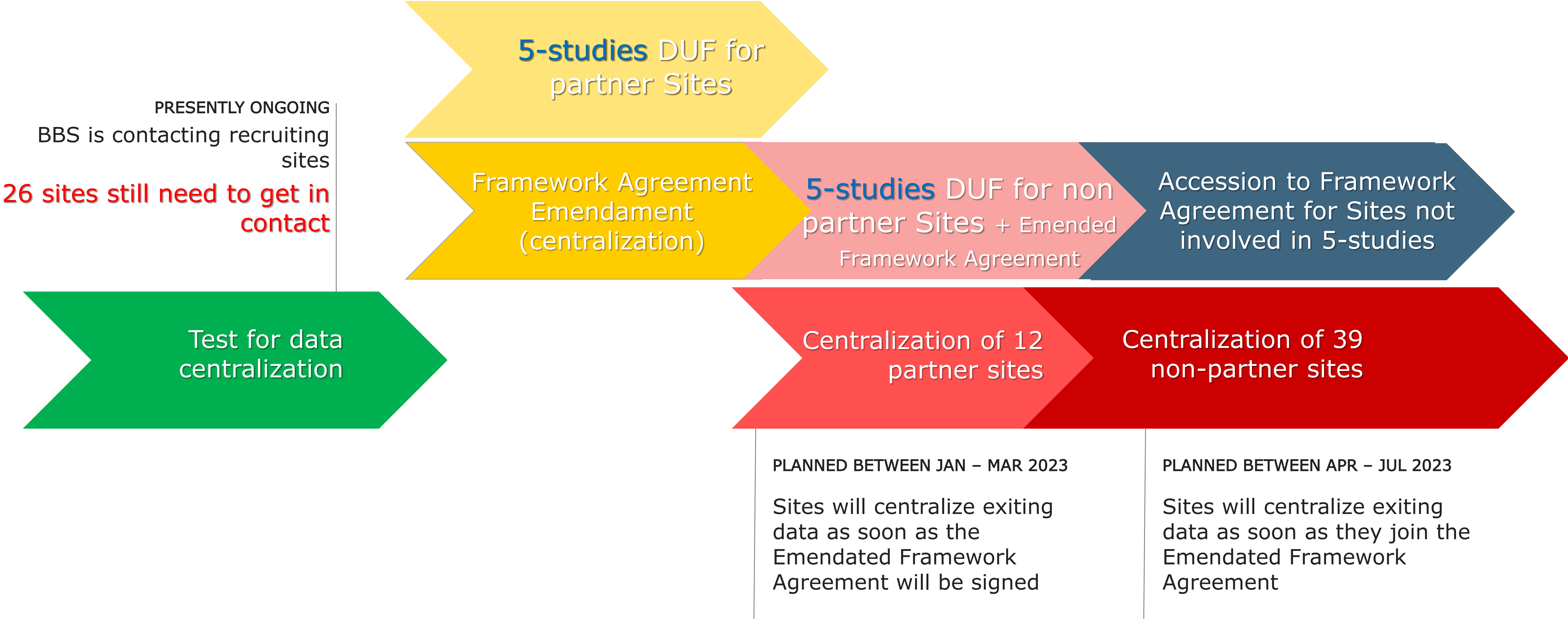


IT CENTRALIZATION

TARPSWG

CENTRALIZATION OF RESAR

ONLINE RESAR PLATFORM EXTRA



- OPERATION ▾
- View patients

Import data

Researchers

Dashboard

View patients

The list of your patients

Go to page

New patient

Fill the fields to insert the profile

Go to page

Import data

Import patients from CSV/Excel

Go to page

Researchers

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

Fields

This is the list of the form fields

Go to page

Studies

Go to page

Quality Check

Go to page

Summary

Go to page

OPERATION ▾

- View patients
- New patient
- Import data
- Researchers

ADMIN TOOLS ▾

- Rules
- Hospitals
- Users
- Fields
- Studies
- Quality Check
- Summary

Insert patient

Back to Patient List

DEMOGRAPHICS

Original PatientID

Insert original patientid to anonymize

Check ID

Sex

Hospital

Country of origin

Enter the age or calculate it by entering birth Date and date of first biopsy or first surgery

Birth Date

gg/mm/aaaa

Date of first biopsy or surgery

gg/mm/aaaa

Age

Please insert time at date of diagnosis or surgery

Consent to participate

Yes/No/NA

☐ Yes

☐ No

☐ Not Applicable

ECOG performance status at time of consent

☐ 0

☐ 1

☐ 2

☐ 3

☐ 4

Race

White / Black / Asian / Latino / Other

☐ White

☐ Black

☐ Asian

☐ Latino

☐ Other

Date consented to participate

DD/MM/YYYY

gg/mm/aaaa

RESAR Studies

TARPSWG

Ongoing RESAR projects: «the 5 studies»

Study	ID	PIs	Study time-frame	Participating Centers	Statistician
BISARC	R1905	S. Dumitra A. Gronchi	Jan 2017 – Jan 2020	21	TBD
Patterns of Care	R2005	H. Snow D. Gyorki	Jan 2017 – Jul 2022	29	Sophia Xie (Melbourne)
Response to Neoadjuvant	R2007	W. Van Houdt A. Gronchi S. Reijers	Jan 2017 – Oct 2020	19	TBD
ResAntiPath	R2006	M. Fiore A. Gronchi D. Strauss	Jan 2017 – Jan 2020	22	R. Miceli (Milan)
Benchmarks	R1906	A. Gronchi F. Tirotta M. Fiore	Jan 2017 – Dec 2021	24	TBD



5-STUDIES DATA FLOW

5-studies: BISARC, Pattern of Care, Response to Neoadjuvant, ResAntiPath, Benchmarks

PRESENTLY ONGOING

3 sites signed
3 sites pending

5-studies DUF for
partner Sites

PLANNED BETWEEN JAN – MAR 2023

Sites will centralize 5-studies
data as as soon as they will sign
DUF
No modification to contracts will
be possible

Complexity Score
Study

Framework Agreement
Emendament
(centralization)

5-studies DUF for non
partner Sites

Accession Document to
Emendated Framework Agreeemet
+ DUF

DUF Signature

SITE WILL SEND EXCEL
FILES TO INT (1 EXCEL
FOR EACH STUDY)

INT WILL MERGE 5 FULL
DATASETS (1 DATASET FOR EACH
STUDY)

INT WILL SEND DATASET TO
STUDY PI FOR ANALYSIS

R-1905

R-2005

R-2007

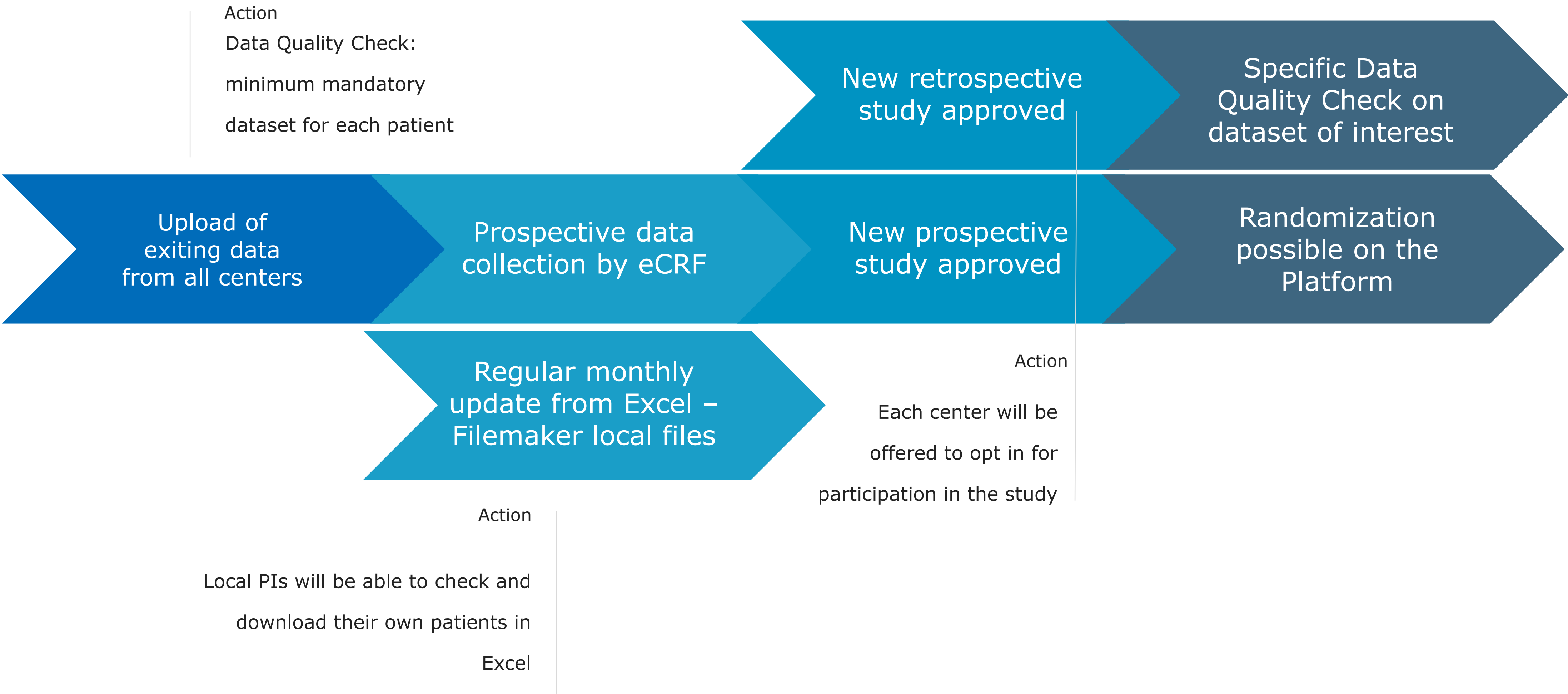
R-2006

R-1906

HOW Centralized RESAR WILL WORK



A PROSPECTIVE OBSERVATIONAL CONTROLLED STUDY



FOR NEW CENTERS: HOW TO JOIN RESAR

OPEN TO ANY TARPSWG CENTER



DECLARATION OF INTEREST

Please contact:

marco.fiore@istitutotumori.mi.it

tarpswg@gmail.com

FOR DATA TRANSFER AGREEMENT

Contact

marco.fiore@istitutotumori.mi.it

daniela.salvatore@istitutotumori.mi.it

DOCUMENTS: STUDY
PROTOCOL, DATASET

LOCAL IRB
APPROVAL

JOIN EMENDED
FRAMEWORK AGREEMENT

CENTER
ACTIVATION

FIND MATERIALS AND DOWNLOAD HERE:

tarpswg.org/resar-study-documentation

LOGIN FOR EXTRA
PLATFORM FOR ONLINE
DATA ENTRY WILL BE
RELEASED