

Giornate **AIEOP**

BOLOGNA

Zanhotel Europa

14-15 Aprile 2025

Tumori cerebrali
Maura Massimino

Fondazione IRCCS Istituto Nazionale dei Tumori
(Milano)

Disclosures of Name Surname

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other
Oncoscience			X				

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TC e Riunioni recenti

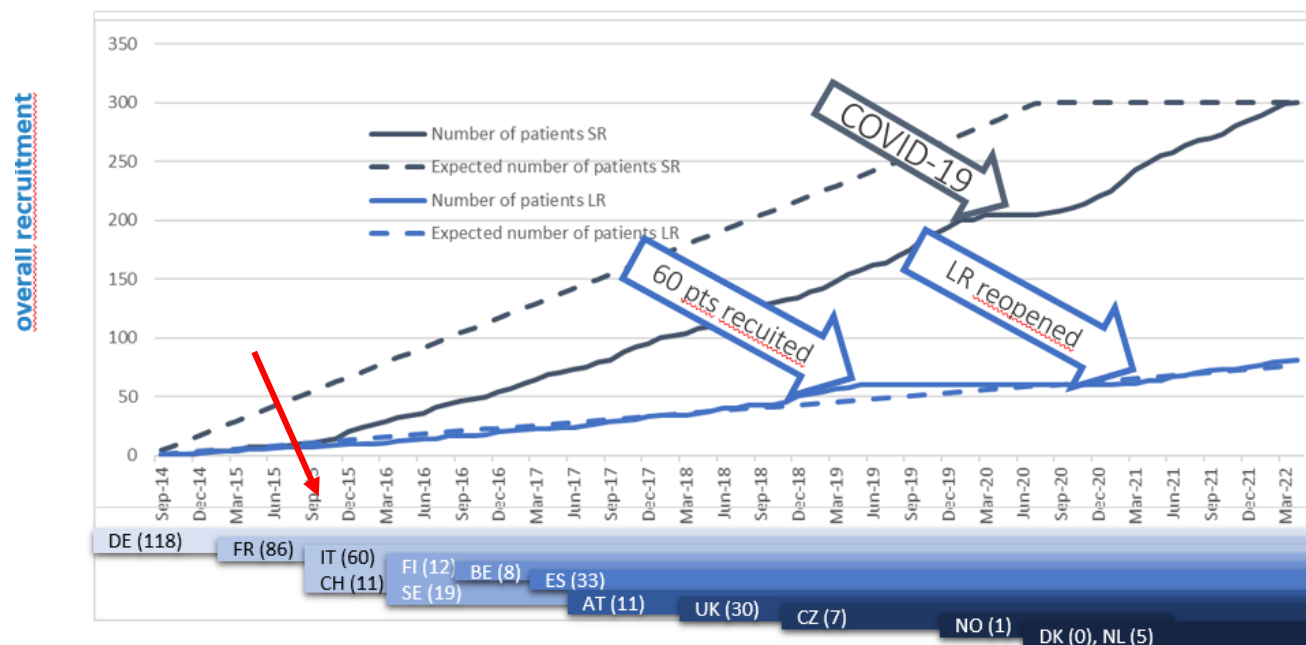
- Riunione per studio biologico DIPG 29/10/2024
 - (non condiviso come AIEOP)
- Riunione open del GdL 25 marzo 2025
- Riunione SIOPe HGG 27.28 marzo 2025
- Aggiornamenti relativi ai protocolli aperti
- Plurime consulenze/discussioni casi per mail/telefoniche/*de visu*

Programma odierno

- Aggiornamento protocolli aperti
 - Medulloblastoma
 - Diversi gruppi di rischio
 - Ependimoma
 - Gliomi a basso grado
 - Protocolli (ancora) in apertura
 - Tumori teratoidi/rabdoidi atipici
 - Medulloblastoma < 3 aa alla diagnosi
 - Quasi al traguardo protocollo HGG SIOPe
 - Protocollo osservazionale tumori cerebrali AIEOP
 - Fase/i 2 e 1
-

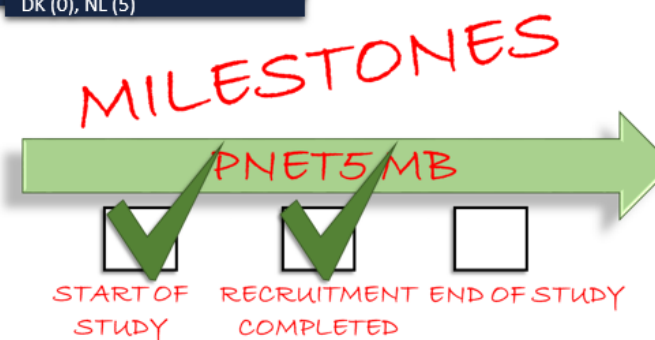
PNET 5 e MB6

PNET 5 – recruitment complete since March 2022



PNET 5 MB	Final status 04/2022
LR	81
SR	300
WNT-HR	11
SHH-TP53	6
Registry	3
all	401

Italia:
50 SR
10 LR



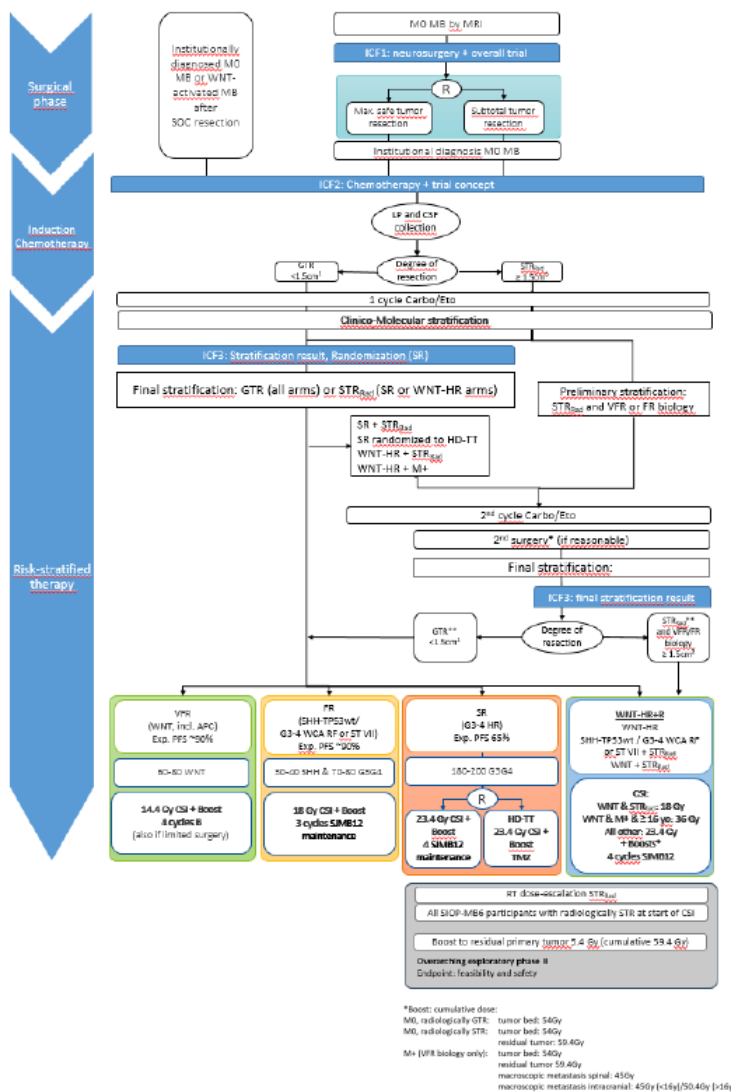
PNET 5 – current recommendations of the SIOP-PNET5-MB study group for standard risk medulloblastoma

PNET5 risk group	Treatment recommendation	Comment
Low-Risk	23,4 Gy CSI 54.0 Gy boost (total dose) 6 x maintenance therapy (e.g. BA BA BA)	18 Gy CSI not justified outside the trial VCR during RT: no evidence for the safety of omission (but efficacy not proven) Maintenance: 6 cycles BABABA reasonable (or national standard)
Standard-Risk	23,4 Gy CSI 54.0 Gy boost (total dose) 8 x maintenance therapy (e.g. BA BA BA BA)	Carboplatin is <u>not</u> the current standard VCR during RT: no evidence for the safety of omission (but efficacy not proven) Maintenance: 8 cycles BABA reasonable (or national standard)
WNT-High-Risk (WNT with any HR-feature)	National HR concept	CSI dose de-escalation not recommended outside clinical trials
SHH-TP53mutated (any clinical staging)	National HR concept	Very-high-risk disease even in M0R0 Germline analysis recommended Therapy according to PNET5 SHH-TP53 arm can be considered (contact Till Milde for individual recommendation)

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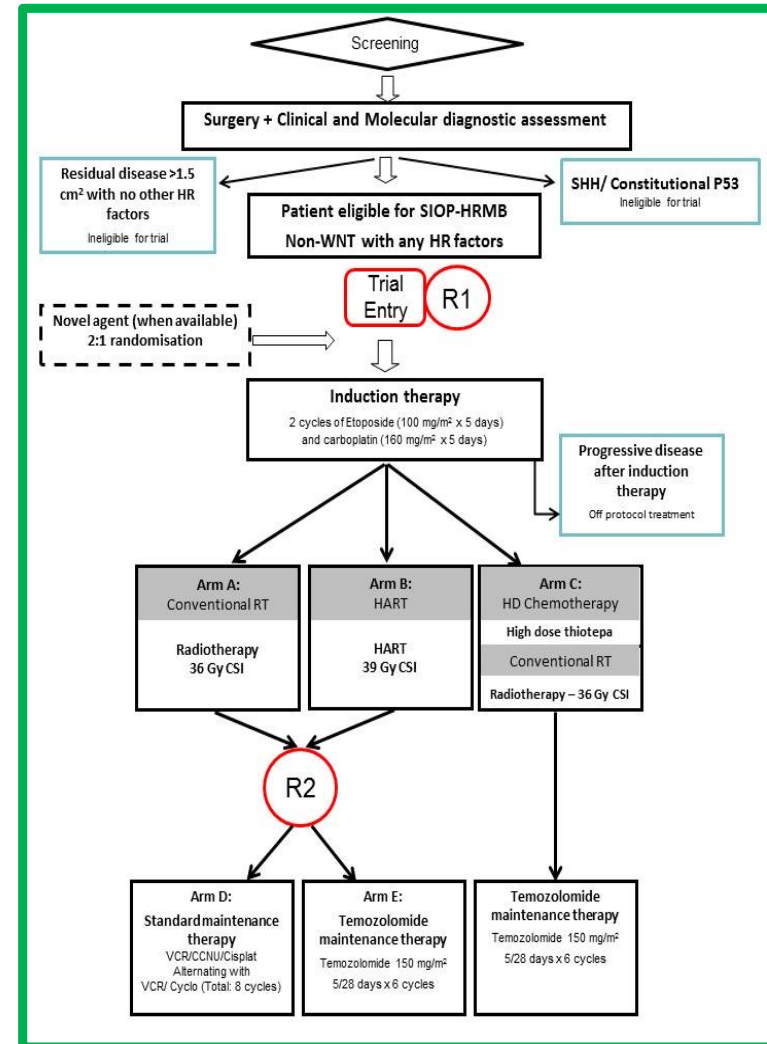
SIOP MB6



Total No patients	~380
Trial duration	6 (-8) years
Participating countries	SIOP-E
Sponsor	Germany

SIOP HRMB Trial

- Medulloblastoma (MB) is the most common malignant brain tumour in children and young people accounting for 20% of all brain tumours in children. Around 30% of MB patients are diagnosed as High-risk MB (HR-MB)
- Phase III
- Children, teenagers and **adults** with newly diagnosed “high risk” medulloblastoma
- Screening phase
- 2 randomisations



Inclusion criteria – trial entry and R1

- Histologically proven (**centrally reviewed**) HR-MB with any of the currently defined histological subtypes
 - **SHH subgroup** or **non-SHH/non-WNT** (Groups 3 and 4)
 - With **at least one** of the following:
 - **Metastatic disease:** Chang stage M1, M2 and M3
 - **Large cell/Anaplastic MB** (defined by WHO criteria 2016)
 - **Significant residual tumour** (> 1.5 cm²) following surgical resection of primary tumour and **other biological risk factors**
 - **Patients with MYC or MYCN amplified tumours** (unless MYCN amplified Group 4 without any other risk factors)
 - Patients with **SHH** subgroup tumours harbouring **somatic TP53 mutations**
 - Age ≥ 3 years
 - **Submission of biological material**, including fresh frozen tumour samples and blood
 - **No prior treatment for MB**, other than surgery, with the exception of one cycle of induction chemotherapy
-

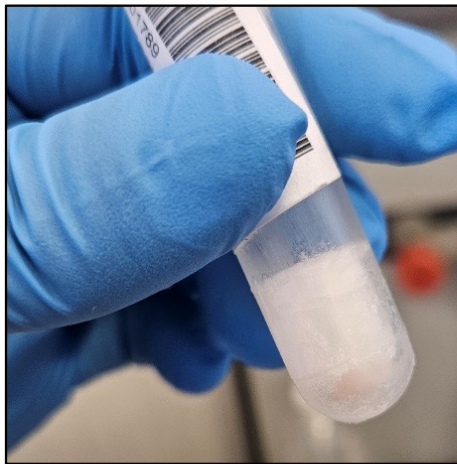
Quality and quantity of frozen sample shipment



Inadequate shipping



Small tissue $<10 \text{ mm}^3$
Large/normal tissue $>3 \text{ cm}$



Frozen Tissue - Tumour material

- Size should be **$> 10 \text{ mm}^3$**
- A minimum of **7.5 mm^3** is required for submission to the International Biological Research Coordinating Centre for trial
- Tissues should be snap-frozen in liquid nitrogen immediately (i.e. maximum 30 minutes post-resection)
- Time between surgery and sample freezing should be recorded.
- The frozen tissue should be stored in liquid nitrogen or at **-80°C** , until ready for dispatch to the National Reference Centre.

Blood samples - Whole blood sample

- **5-10 ml** in EDTA or Na citrate tube
- Collected at any time before the start of chemotherapy
- Stored to extract constitutional DNA as control material for genomic analyses performed on frozen tumour tissue and for research studies on germline mutations
- Ship immediately to National Reference Center at **4°C** or keep at **-20°C** and ship frozen to National Reference Center

SIOP HRMB sept 2022-feb 2025: report

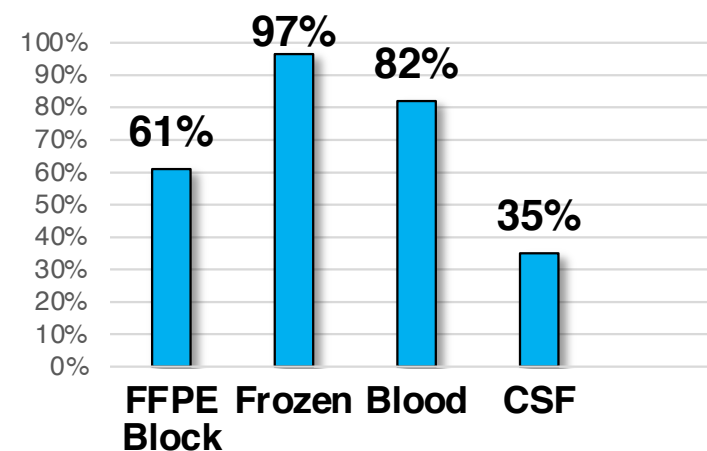
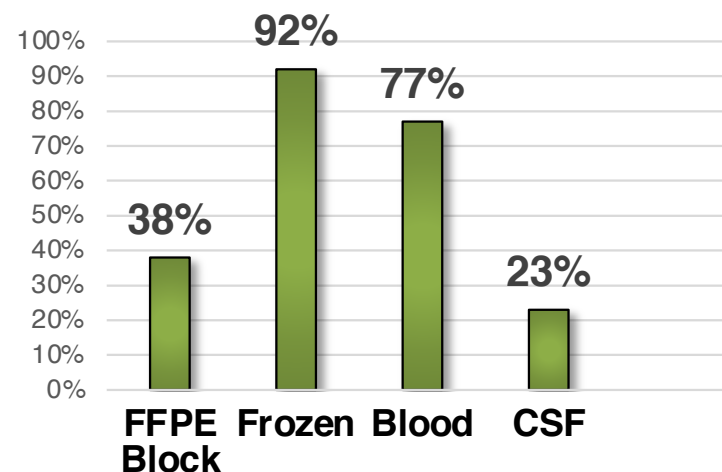
2024

	Cases n°	FFPE Block n°	Frozen n°	Blood n°	CSF n°
All Enrolled	13	38%	92% 1 not usable	77%	23%



2025

	Cases n°	FFPE Block n°	Frozen n°	Blood n°	CSF n°
All Enrolled	30	61%	96.5% 1 not usable	82%	35%



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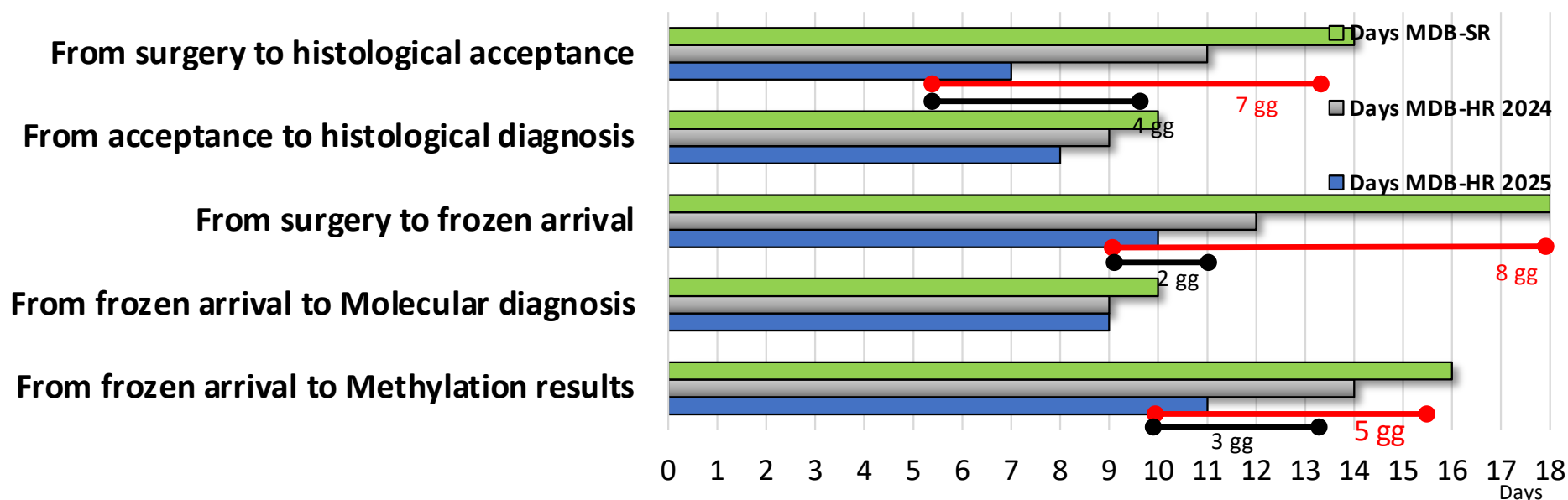
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TAT PNET5-SR	Days Average	Days St.Dv
From surgery to histological acceptance	14	7
From histological acceptance to histological diagnosis	10	6
From surgery to frozen arrival	18	7
From frozen arrival to Molecular diagnosis	10	7
From frozen arrival to Methylation results	16	9

TAT SIOP HRMB	Days Average	Days St.Dv
From surgery to histological acceptance	11	5
From histological acceptance to histological diagnosis	9	4
From surgery to frozen arrival	12	4
From frozen arrival to Molecular diagnosis	9	4
From frozen arrival to Methylation results	14	5

TAT SIOP HRMB	Days Average	Days St.Dv
From surgery to histological acceptance	7	3
From histological acceptance to histological diagnosis	8	5
From surgery to frozen arrival	10	4
From frozen arrival to Molecular diagnosis	9	3
From frozen arrival to Methylation results	11	5

Days of Enrolled MBs



Open NCCs

Country	Date Activated	No. of Open Sites	No of Patients Registered for Screening	No of Patients Recruited (R1)
Austria	05-Nov-2021	4	1	1
Belgium	31-Oct-2022	7	10	1
Czech Republic	08-Mar-2024	1	0	0
Denmark	25-Mar-2022	3	3	3
Finland	07-Feb-2024	4	2	0
Germany	01-Aug-2023	32	9	8
Italy	24-Mar-2022	10	33	23
The Netherlands	22-Apr-2022	2	5	3
Norway	27-May-2022	3	3	3
Sweden	23-Apr-2023	4	3	3
Switzerland	30-Nov-2021	9	7	1
UK	19-Jan-2021	18	70	31

Centralizzazione radioterapica, Quartet

QUARTET SITE APPROVALS/ICR

QUARTET RTQA Site Approvals

So far 35 institutions have completed the required site RTQA approval procedures, with a further 8 in progress. Site RTQA approvals are underway in Belgium, Czech Republic, Denmark, Finland, Germany, Italy, Netherlands, Norway, Sweden, and the United Kingdom.

ICR Case Review summary

- * 60 cases reviewed (as of March 3rd)
- * 28% (stable) required some kind of resubmission, mainly due to delineation
- * Feedback is being acted upon by sites

Siti Operativi:

- Milano
- Roma
- Napoli
- Genova

-On going/pronti all'arruolamento:

- Udine/Aviano
- Torino
- Bari
- Catania
- Padova
- Bologna

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NATIONAL COORDINATING CENTRES SET-UP

The SIOP-HRMB trial is an international collaboration of coordinating teams based all over Europe. Including the UK, we have 16 participating countries, all at different stages of setting up the trial.

 AUSTRIA 5 Sites Planned NCC AGREEMENT SIGNED	 BELGIUM 8 Sites Planned NCC AGREEMENT UNDER REVIEW	 CZECH REPUBLIC 2 Sites Planned	 DENMARK 3 Sites Planned NCC AGREEMENT UNDER REVIEW
 FINLAND 5 Sites Planned NCC AGREEMENT UNDER REVIEW	 FRANCE TBC Sites Planned	 GERMANY 60 Sites Planned NCC AGREEMENT UNDER REVIEW	 ITALY 12 Sites Planned NCC AGREEMENT UNDER REVIEW

10/12 aperti

Milano, 8 pazienti

Napoli, 7 pazienti

Roma BG, 7 pazienti

Genova, 1 paziente

 THE NETHERLANDS 2 Sites Planned NCC AGREEMENT UNDER REVIEW	 NORWAY 4 Sites Planned NCC AGREEMENT UNDER REVIEW
 PORTUGAL 3 Sites Planned	 REPUBLIC OF IRELAND 1 Site Planned
 SPAIN TBC Sites Planned	 SWEDEN 6 Sites Planned
 SWITZERLAND 9 Sites Planned NCC AGREEMENT SIGNED	 THE UK 21 Sites Planned <u>5 Sites Activated</u>

SIOP EPENDYMOMA II

An International Clinical
Program for the diagnosis and
treatment of children,
adolescents and young adults
with Ependymoma

EudraCT number: 2013-002766-39

Clinical Trials number: NCT02265770

VHP number: VHP201385

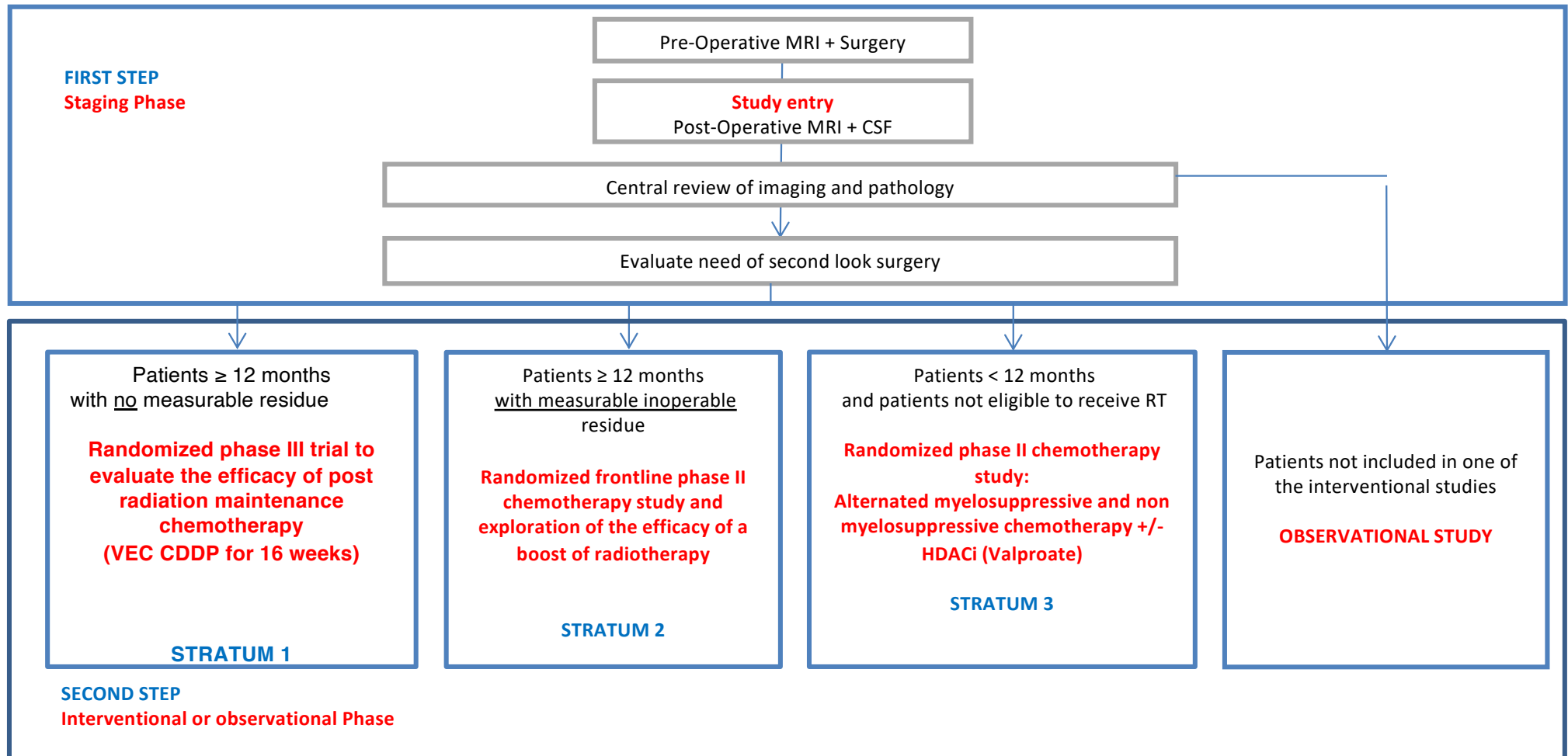
SIOP EP-II in Europe



**15 Participating
countries**

**Protocol version 4.0
dated 11/07/2022**

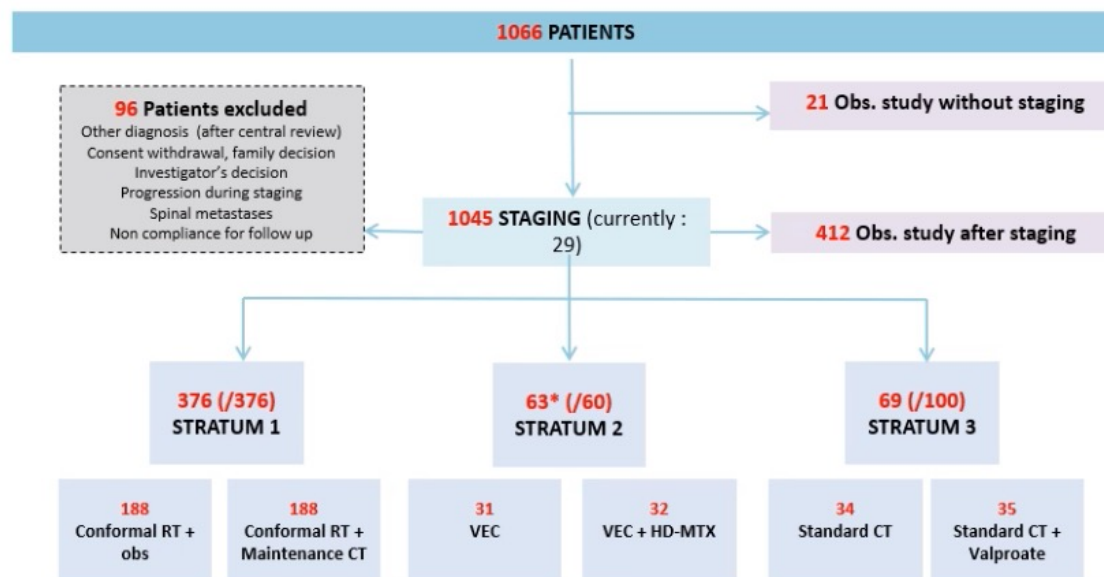
Study design



Overall recruitment

(March 31st, 2025)

EUROPE



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Overall recruitment June 10 th , 2024	Staging	Obs.	Stratum 1	Stratum 2	Stratum 3	Exclude d	Tota l
Austria	0	3	9	0	0	1	13
Belgium	3	15	12	4	2	5	41
Czech Republic	0	7	8	0	5	0	20
Denmark	0	2	2	1	0	0	5
Finland	0	3	1	0	0	0	4
France	6	85	80	5	7	34	217
Germany	2	60	42	9	3	1	117
Greece	0	2	1	0	0	0	3
Ireland	0	5	3	0	4	0	12
Italy	5	33	88	10	2	9	155
Norway	0	2	3	0	0	0	5
Spain	4	28	36	13	5	10	96
Switzerland	1	12	2	2	2	4	23
The Netherlands	3	10	5	1	0	2	20
UK	3	106	68	18	37	24	256
TOTAL			376	63*	69		
TARGET			376	60	100		

= 1066

*60 evaluable patients / 63

Ependimoma Stratum II Italia

- Valutazione della storia radiologica dei pazienti con Ependimoma arruolati nello STRATUM II in Italia dal 2016 al 2024
- 10 pazienti (3 non valutati per imposizione)
- 7 pazienti : 4 femmine, 3 maschi
- Eta' media all'esordio 5, 8 anni (range 3-10)
- Il look chirurgico in 5 /7

Presence of residue:

☐ R0 : No residual tumour on postoperative MRI in accordance with the neurosurgical report

☐ R1 : No residual tumour on MRI but description of a small residual tumour by the neurosurgeon or if the neurosurgical result is unknown

☐ R2 : Small residual tumour on MRI with the maximum diameter below 5mm in any direction

☐ R3 : Residual tumour that can be measured in 3 planes

☐ R4 : Size of the residual tumour not differing from the preoperative status (e.g. after biopsy)

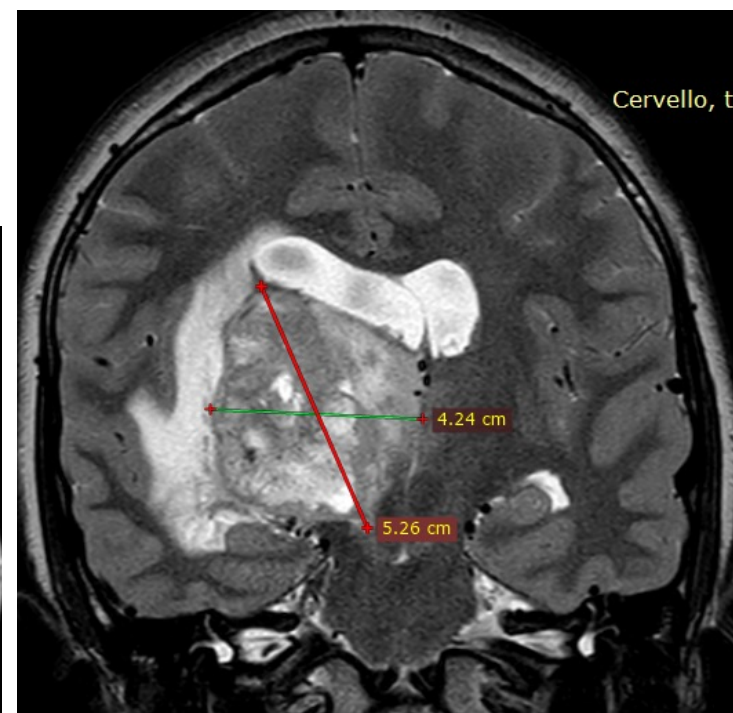
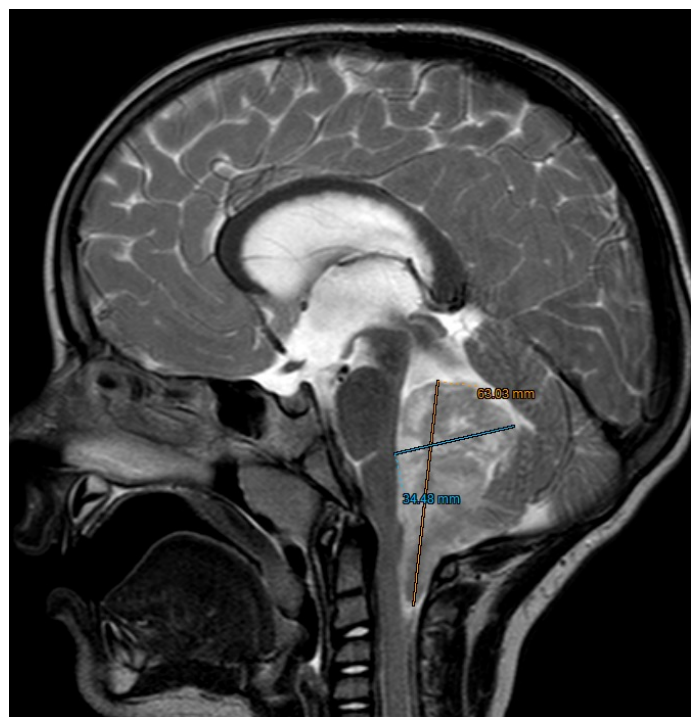
☐ RX : If imaging is inadequate or the surgical cavity is very confusing also the term "unclear" should be possible

ID studio	Randomizzazione	Pre chir	Post chir	Post second look	Post CT	Post RT
002	05/04/2022	22/02/2022 e 28/02/2022 (midollo)	04/03/2022 28/3/2022 27/4/2022 17/5/2022 Stealth	23/5/2022 residuo mm (AP 29.50 LL 13.19 CC 36.02; LL 19)	??	??
003	19/05/2022	05/04/2022	11/04/2022	22/04/2022 Residuo cm (AP 2.27; LL 1.13; CC 2.38)	??	??
001	25/10/2021	13/09/2021	(intervento 17/09/2021) Residuo mm I (AP 4.77; LL 8.40)	(secondo intervento 24/09/2021) Residuo mm (AP 9.16; LL 7.03)	Residuo asportato completamen te 3/1/2022	RM 18/5/2022 Non residui misurabili e form cistiche sinechiali
018	05/11/2021	12/09/2021	21/09/2021 Residuo mm (AP 9.61, LL 10; CC 8.08)	28/10/2021 Persistenza di lesione mm (AP 6.43; LL 8.81; CC 8.49)	07/01/2022 Residuo mm (AP 10.9; LL 5.82; CC 9.10). Compat sa di nuovo nodulo sul profilo bulbare mm (AP 4.38; CC 8)	6/5/2022 dopo RT resi sostanzialmente invar
002	11/05/2018	31/03/2018	05/04/2018	Not done	16/08/2018 residuo sostanzialmen te invariato cm (AP 2.25; LL 2.73; CC 2.27)	27/11/2018 Residuo ridotto AP 1.44; CC 1.37
004	03/06/2016	01/05/2016	09/05/2016	06/09/2016	11/08/2016 residuo mm (AP 30.4; LL 28.3; CC 37.3)	19/12/2016 residuo ridotto 2.15; LL 1.23; CC 3.
011	15/03/2017	15/01/2017	18/01/2017	Not done	08/05/2017 residuo mm (AP 15.3; LL 8.01; CC 15.04)	30/08/2017 residuo ridotto 10.7; LL 7.18; CC 6.

Revisione della storia
radiologica dei pazienti italiani
con ependimoma inclusi in
STRATUM II

Sede della lesione

- Sottotentoriale 6
- Sopratentoriale 1
- Disseminazione 0



Risultati

Pz 1	R3		R3-SD	R3-SD	CR	R2
Pz 2	R4		R3-SD	R3-SD	PR	
Pz 3	R3		R3-SD	R3-SD		
Pz 4	R3		R3-PR	R3-PR		
Pz 5	R3		PD	R3-SD	PR	
Pz 6	R3		R3-SD	R3-PR		
Pz 7	R3		R3-SD	R3-PR		

SD Stable disease; PR partial response; PD Progression disease; CR complete response

EPENDIMOMA PF

Originano dal pavimento del IV ventricolo, raramente dal tetto.

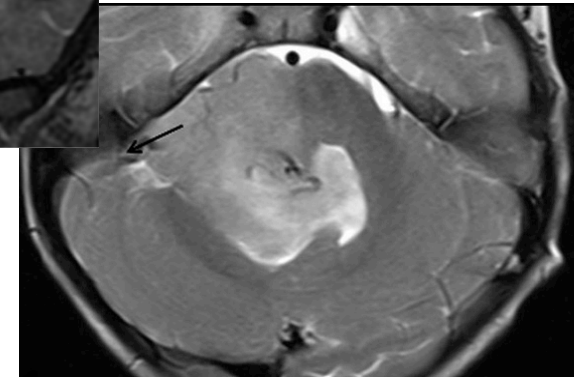
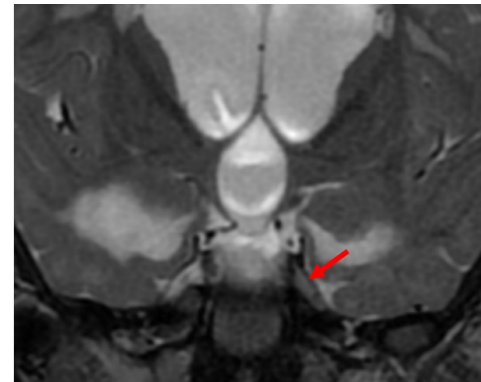
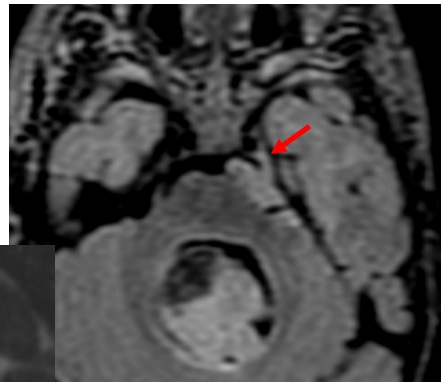
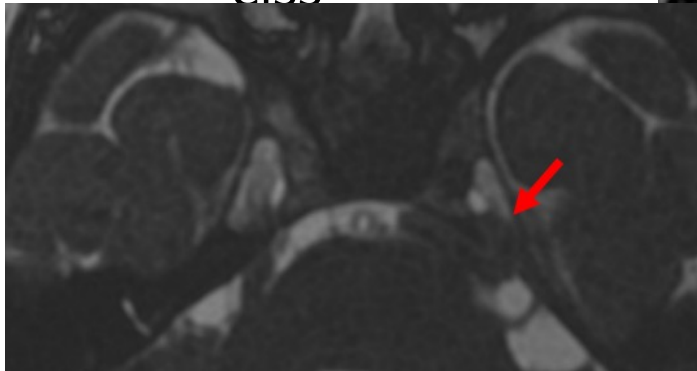
EPF hanno caratteristiche PLASTICHE e propensione a crescere ed estendersi attraverso i forami di Luschka e Magendie insinuandosi negli spazi liquorali attorno al tronco

Riempiono e distendono il IV ventricolo (idrocefalo nel 90% dei casi)

tendono ad avvolgere (ENCASING) vasi e nervi cranici, rendendo difficile la resezione chirurgica totale (il fattore prognostico PIU' importante per la sopravvivenza)



CISS



Criticità

- Sede della lesione
 - Radicalità dell'intervento
 - Protocolli RM post-operatori adeguati per valutare l'eventuale residuo (sede, strutture adiacenti e dimensioni)
 - Importanza dell'uso delle sequenze volumetriche T2 pesate (CISS, DRIVE.....)
 - Indicazioni di follow-up in caso dubbio
-

BIOMECA-2: Work packages

- Annotation of BIOMECA cases in SIOP EPN II with core and core⁺ tests to address the questions:
 - Does chromosome 13q loss confer poorer PFS in PFB ependymoma?
 - Are epigenetically defined PFA subtypes associated with different survival outcomes?
 - Are chromosomal abnormalities (1q gain/6q loss) subtype specific in their association with poor outcome?
 - Are non-RELA::ZFTA fused supratentorial ependymomas associated with poorer survival?
 - Does homozygous CDKN2A deletion confer adverse prognostic significance in ST ependymomas?
 - Are subclonal tumour regions containing chromosome 1q gain or 6q loss predictive of an increased risk of relapse and death?
 - CSF Analyses
-

Italy – tumor tissue collected

- 92 FFPE
 - (of which 61 molecularly classified MA)
- Additional 46: unstained slides/rolls
 - (i.e. limited material)

SIOPE DIPG/DMG Registry Update



SIOPE Europe
the European Society for Paediatric Oncology

DIPG/DMG Registry

[Privacy Statement SIOPE DIPG Registry](#)

SIOPE DIPG Registry Documents

[Protocol v.2.0_2022-09-08](#)

[Regulatory Document v.3.0](#)

[Bylaws v.1.2_2022-09-08](#)

[Submit research proposals](#)

[Research proposal application form](#)

Welcome to the SIOPE DIPG Registry

Children suffering from Diffuse Intrinsic Pontine Glioma ("DIPG") or face a dismal prognosis with a median survival of less than 1 year from diagnosis. Treatment options for children with DIPG are limited; due to its delicate location in the pons, the tumor cannot be removed surgically. Also, an alleged resistance to chemotherapy, possibly due to an intact blood-brain barrier, limits treatment options. Radiotherapy therewith remains the primary treatment approach, although this can only temporarily improve symptoms.

In recent years, more insight has been gained on molecular aberrations in these tumors resulting in the discovery of histone 3 (H3) mutations in DIPG and paediatric high-grade gliomas (HGG). This eventually has led to the introduction of a new genomic based WHO classification known as diffuse midline glioma (DMG) H3 K27-mutant.

The SIOPE DIPG/DMG Network, a network of physicians and researchers throughout Europe, was established to promote and perform excellent research in the field of DIPG/DMG. The Network therefore initiated the SIOPE DIPG/DMG Registry; an extensive database allowing for collaborative research that ultimately will lead to improved survival.

Physicians all over Europe and beyond, treating DIPG/DMG patients, are invited to contribute to this shared objective.

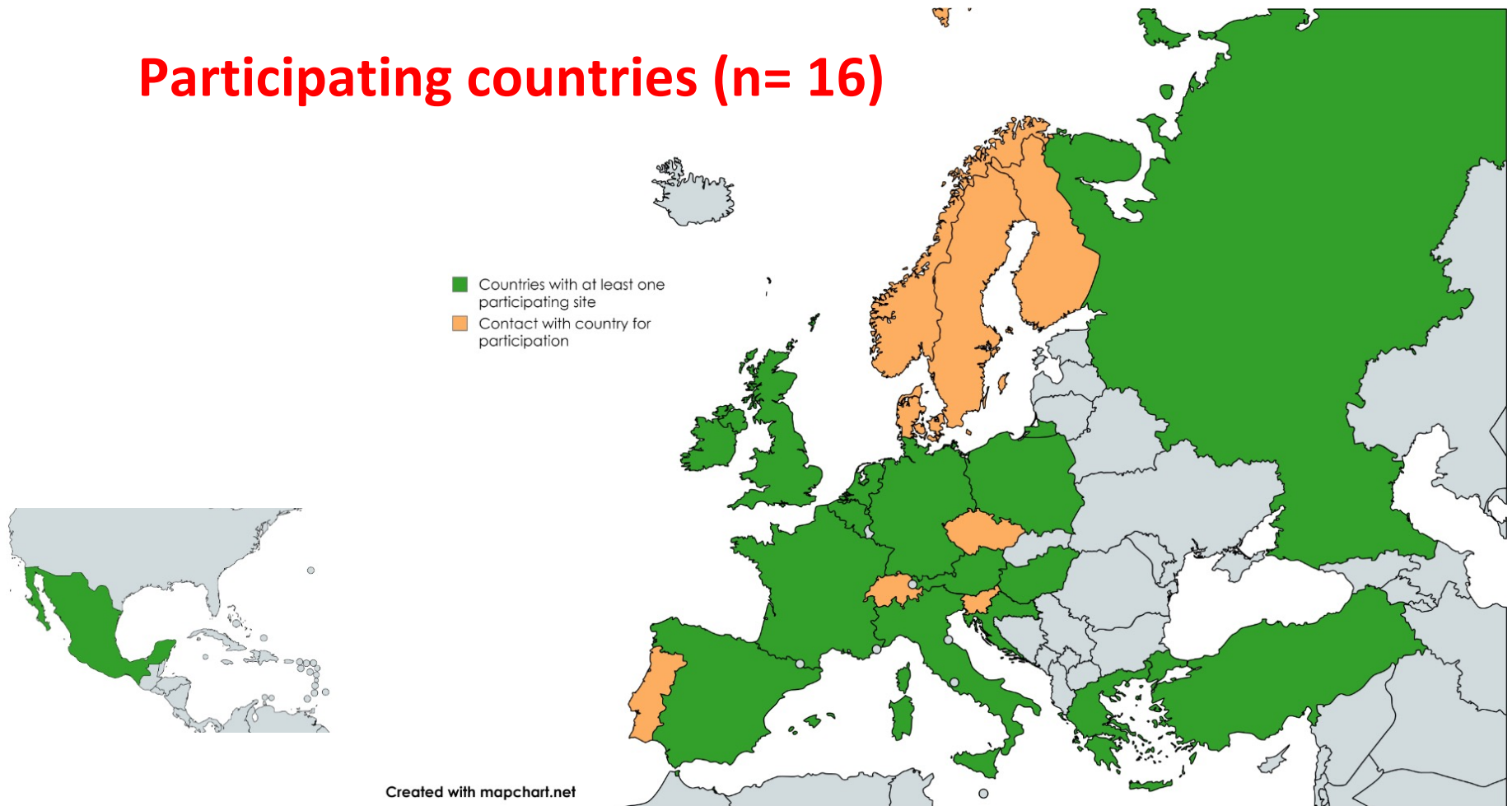
They can use this website to provide their patients' data for research.

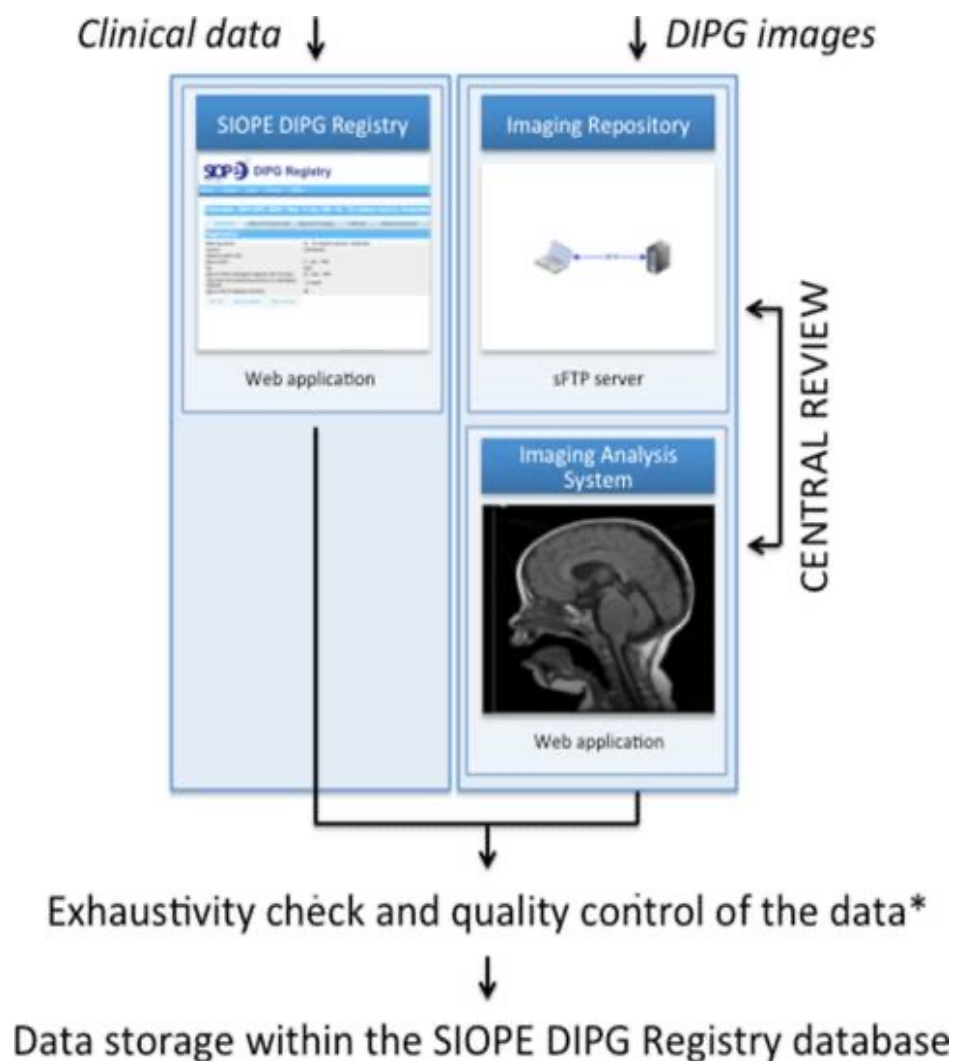
If you are a parent from a child diagnosed with DIPG/DMG, please ask your treating physician about this Registry.

[Proceed to data entry](#)

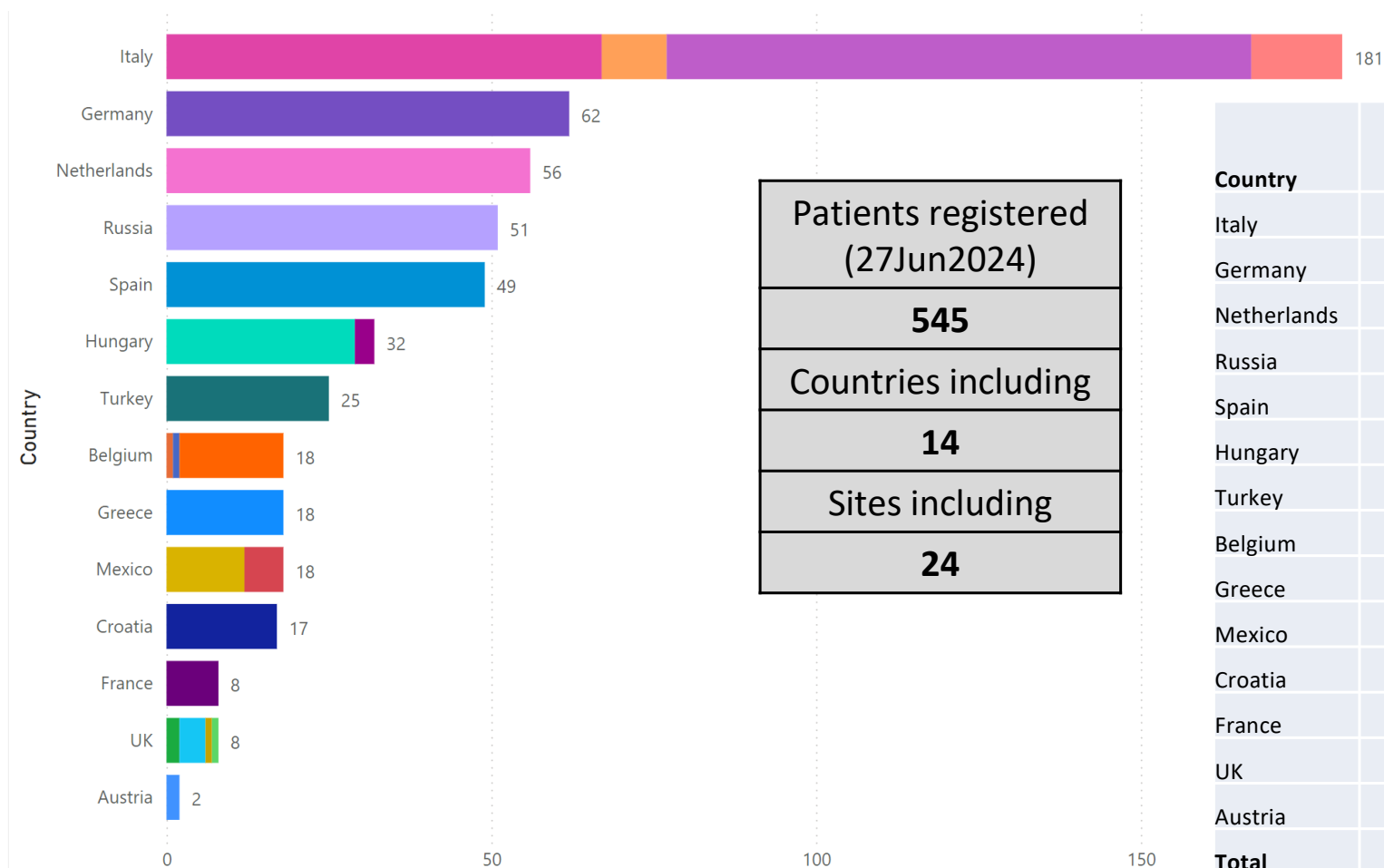


Participating countries (n= 16)





Number of patients by country and hospital



Patients registered (27Jun2024)
545
Countries including
14
Sites including
24

Country	DIPG	Non-pontine DMG	Unknown
Italy	131	11	39
Germany	59	2	1
Netherlands	36	19	1
Russia	51	0	0
Spain	48	0	1
Hungary	32	0	0
Turkey	21	4	0
Belgium	16	2	0
Greece	14	4	0
Mexico	18	0	0
Croatia	15	2	0
France	5	3	0
UK	8	0	0
Austria	2	0	0
Total	456	47	42

ITALY (Update at 19/03/2025)

Centers enrolling (N=4):

- Milan/INT → 74 pts
- Rome/Bambino Gesù → 107
- Florence/Meyer → 8
- Naples/Santobono → 19

208 out of a total of 648 pts (**32%**) in the Registry as started after the Long Term Survivor study back in 2015/2016.

Item	Amount per Donor
Fee per completed and assessable CRF (medical data)	150 €
Fee for complete imaging data (mandatory: diagnostic imaging; preferred: 1 st imaging after RT and imaging at progression)	50 €
Fee for written statement on a link between SIOPE identification Number and tumour material available for future research within the SIOPE DIPG Network	50 €

SIOPE-HGG-01

International cooperative randomized trial of the SIOPE HGG/DIPG Working Group for the treatment of newly diagnosed and recurrent high-grade gliomas in children, adolescents, and young adults

Responsible Pediatric oncologists: Veronica Biassoni, Michael Karremann, Christof Kramm, and Maura Massimino



GESELLSCHAFT FÜR
PÄDIATRISCHE ONKOLOGIE
UND HÄMATOLOGIE



Fondazione IRCCS
Istituto Nazionale dei Tumori
via Venezian, 1 20133 Milano

Sistema Socio Sanitario
Regione
Lombardia

UNIVERSITÄTSMEDIZIN
GÖTTINGEN **UMG**

UMM
UNIVERSITÄTSMEDIZIN
MANNHEIM

General aims of the trial



Option to participate in a clinical trial **close to home**



Establishing a **European platform** with high quality standards

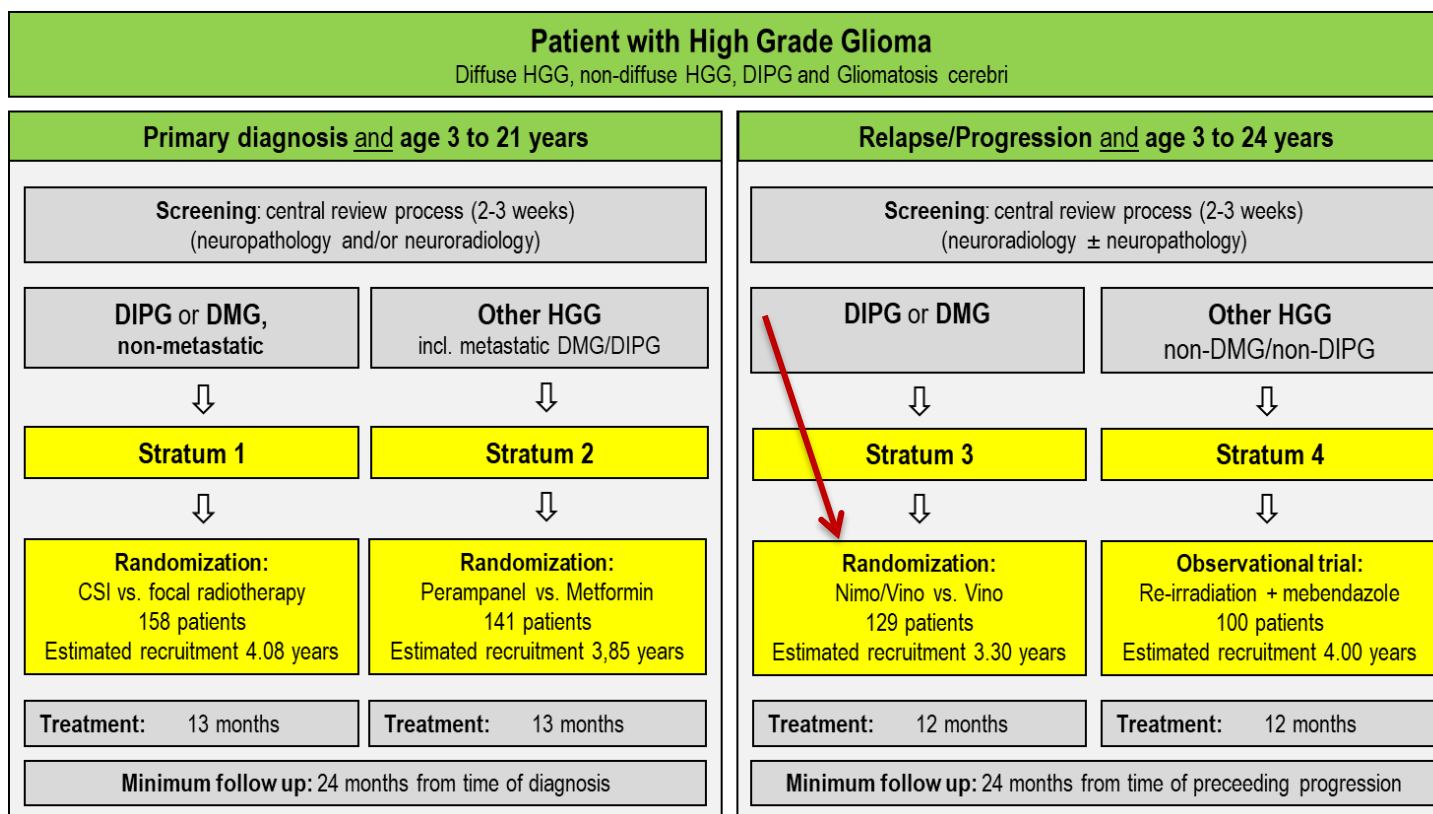


Targeting the **microenvironment**



Study alternative **radiotherapy** concepts

Overview



Countries involved



Austria
Germany
Italy
Switzerland
The Netherlands
Spain

Recruiting: 4
years



Happy to initiate the trial in further countries, once it has been approved by the authorities



Estimated patients per year

	Total/year	Austria	Germany	Italy	Spain	Switzerland	The Netherlands	Recruitment time (years)
Stratum 1	39	2	15	14	4	2	2	4,1
Stratum 2	35	2	12	12	4	2	2	3,85
Stratum 3	40	2	15	14	4	2	2	3,3
Stratum 4	25	2	10	9	2	1	1	4
Total/year	139	8	52	50	14	7	7	

Reference diagnostics

Will be organised OUTSIDE the trial as QC of clinical care

Mandatory, since defined in the I/E criteria

- Reference pathology
- Reference neuroradiology

Optional

- Reference radiation oncological review
→ evaluation as secondary objective and scientific side project

Regulatory issues
Quartet and mdpe

Scientific side projects

- AI-based neuroradiology
- Liquid biopsies
- Molecular tumor evolution
- PDX models
- Immunological evolution
- Quality of life
- Microbiota, Gut-Brain-Axis
- Prediction of radiotherapy response





Funding

By **March 2024**, the protocol has been submitted for funding to the

German Childhood Cancer Foundation

→ **Currently under review**

Financial volume requested

4.141.069 € (7.843 € per patient)

Sponsor will be

German Pediatric Oncology Group, GPOH gGmbH

**KINDER
KREBS
STIFTUNG**



LOGGIC Core BioClinical Data Bank

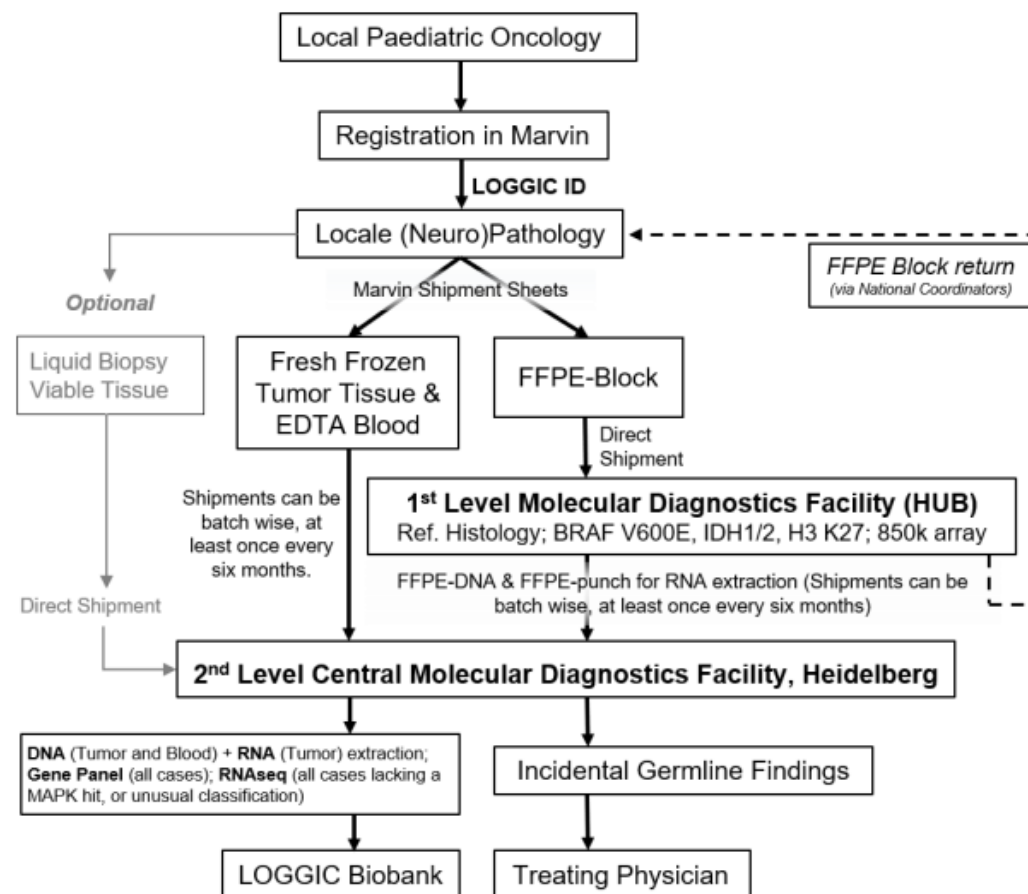


Figure A2: Processes Related to Patient Registration and Sample Shipment in LOGGIC Core.

Recruitment



Figure 1: New registrations per year (as at 28 November 2024).

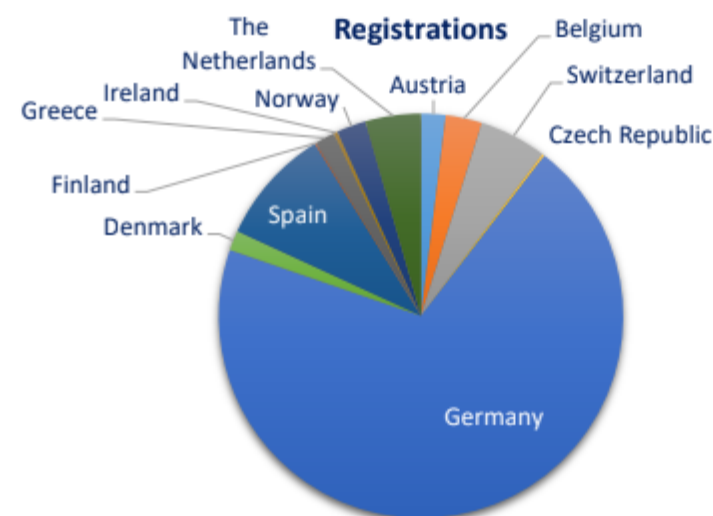


Figure 2: Registrations per participating country since 2019 (as at 28 November 2024).

LOGGIC Core Newsletter 12/2024

1578 patients have been registered in 93 centres from 12 countries.

Contract negotiations are currently underway with the **UK and Italy**.

LOGGIC/FIREFLY-2: A phase 3, randomized trial of tovorafenib vs. chemotherapy in pediatric and young adult patients with newly diagnosed low-grade glioma harboring an activating *RAF* alteration



LOGGIC: Low Grade Glioma In Children

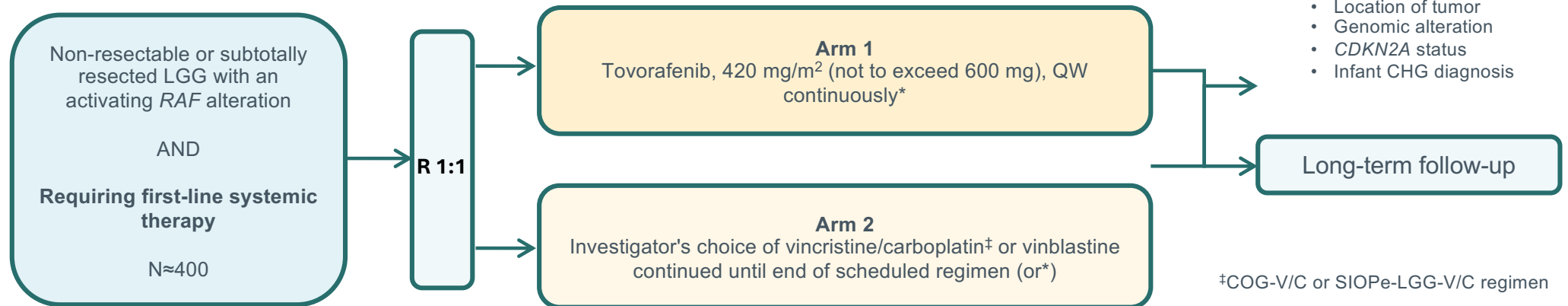


Giornate AIEOP

BOLOGNA 14-15 APRILE 2020



Study Design Overview Firefly2



*Until the occurrence of radiographic progression (based on RANO criteria as determined by the investigator and confirmed by the IRC), treatment completion, unacceptable toxicity, withdrawal of consent to treatment, or end of study

- LOGGIC/FIREFLY-2 is a 2-arm, randomized, open-label, multicenter, global, phase 3 trial
- ~**400 treatment-naïve patients** with a *RAF*-altered LGG are being enrolled from ~130 sites and randomized 1:1 to either tovorafenib (arm 1) or investigator's choice of SoC chemotherapy (arm 2)
- Patients with clinical or radiographic progression in arm 2 will be eligible to cross over to arm 1, should progression occur while on arm 2 treatment or after in long-term follow-up
- Total study length from screening of first patient to end of the study expected to be **approximately 7 yrs[†]**

AGGIORNAMENTO A DICEMBRE 2024

- Middle East, South America sites opening Q2 2025
- Anticipated enrollment completion by **early 2026**



Arruolamento in Italia
(marzo 2025)



SIOPe ATRT01

An international prospective umbrella trial for children with atypical teratoid/rhabdoid tumours (ATRT) including A randomized phase III study evaluating the non-inferiority of three courses of high-dose chemotherapy (HDCT) compared to focal radiotherapy as consolidation therapy

Protocol update



Protocollo SIOPE ATRT01 - timeline

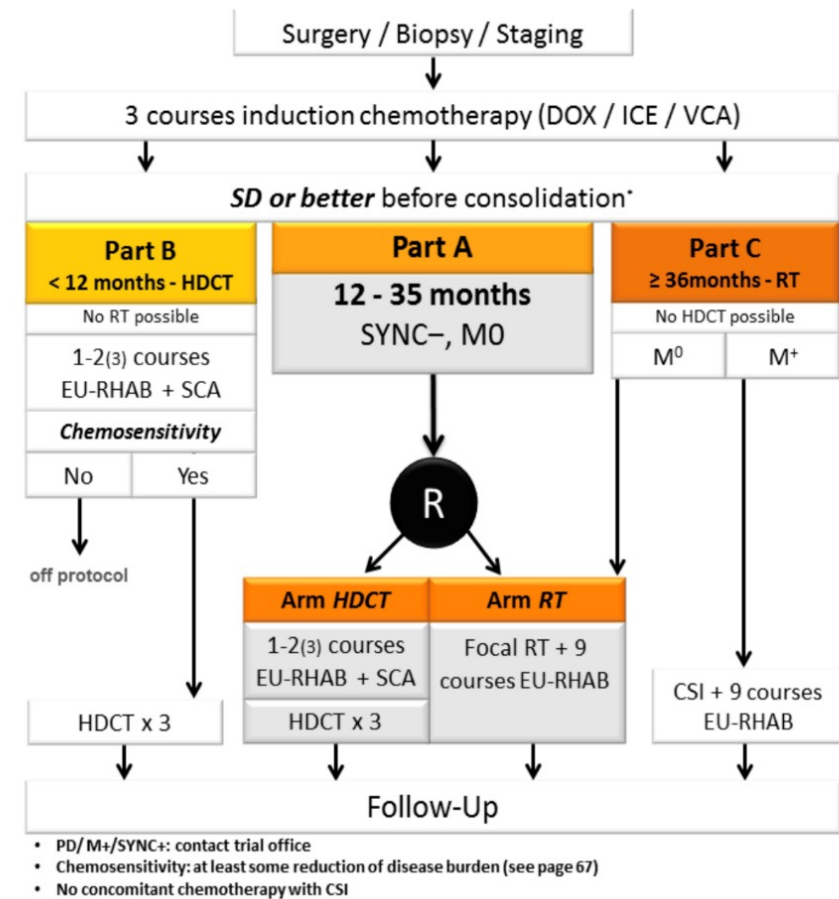


Giornate AIEOP

BOLOGNA 14-15 APRILE 2025

Centro:	Dipartimento	Città	Principal investigator	Stato di attivazione
IRCCS Ospedale Pediatrico "Bambino Gesù"	Area Studi Clinici Oncoematologici e Terapie Cellulari	Roma	Angela Mastronuzzi	Attivo (NCC e centro)
IRCCS Azienda Ospedaliero-Universitaria di Bologna, Policlinico Sant'Orsola	Oncologia ed Ematologia Pediatrica "Lalla Seràgnoli" Clinica Pediatrica	Bologna	Fraia Melchionda	Negoiazione contratto in corso
A.O.U. Città della Salute e della Scienza di Torino - Presidio Infantile Regina Margherita	SC Oncoematologica Pediatrica e Centro Trapianti	Torino	Franca Fagioli	Negoiazione contratto in corso
AORN Santobono-Pausilipon	Oncoematologia Pediatrica	Napoli	Lucia Quaglietta	SIV programmata
IRCCS Istituto Nazionale dei Tumori di Milano	S.C. Pediatria Oncologica	Milano	Elisabetta Schiavello	Negoiazione contratto in corso
Azienda Ospedale Università Padova	UOC Oncoematologia Pediatrica	Padova	Elisabetta Viscardi	SIV programmata

- Umbrella Trial
 - Registrazione
 - Chemioterapia di Induzione
- SIOPE ATRT01
 - Registrazione
 - Stratificazione
 - *Randomizzazione (solo Group A)*
 - Consolidamento
 - Follow-up



INFANT SHH SIOPE (COGNITO MB)

Cohort:

Children <5 years with newly diagnosed non-metastatic, SHH-activated, TP53-wildtype MB

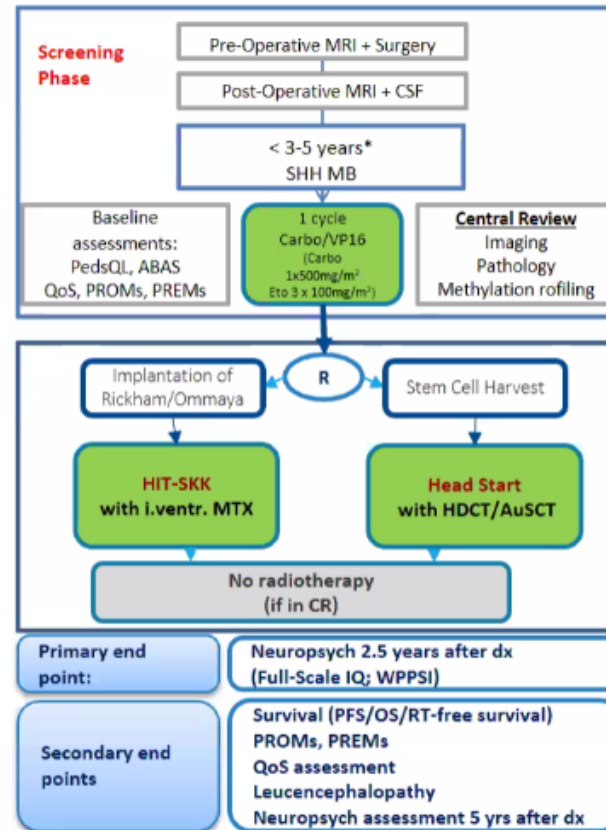
Primary endpoint:

Neurocognitive outcome 2.5 years after initial diagnosis

Randomisation:

Arm A: Head-Start 4
Arm B: HIT-SKK

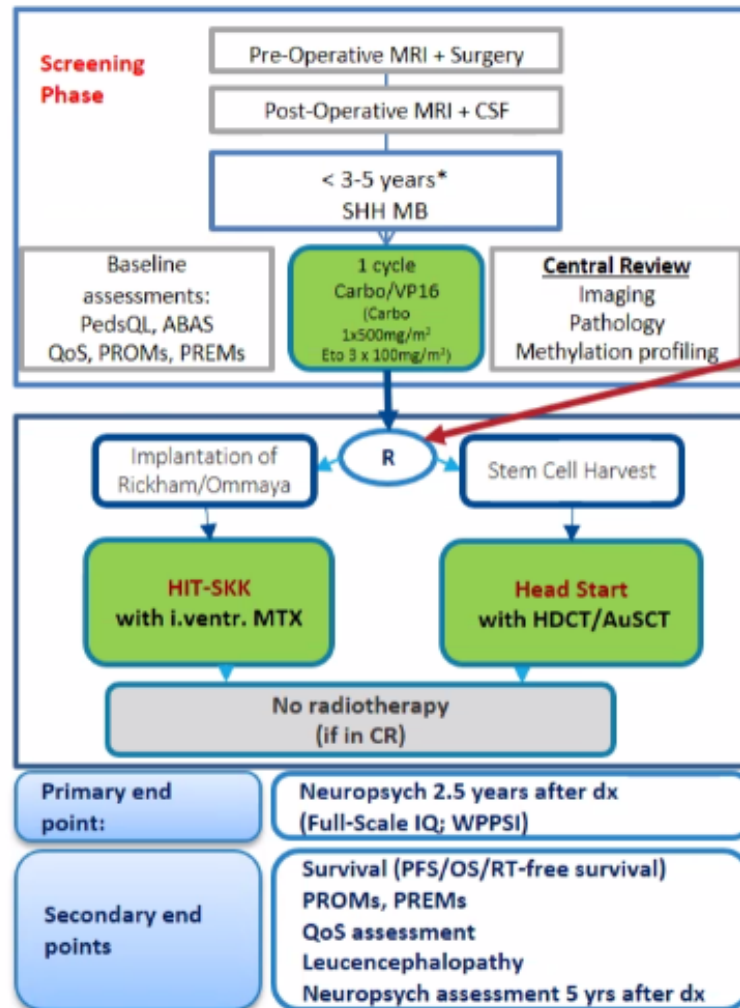
Funding for central parts and Germany: BMBF
(Federal Ministry of Education and Research, Germany)



Co-PIs:

S. Rutkowski, Hamburg, Germany
G. Dhall, Birmingham AL, USA





Stratification: Pediatric Quality of Life + age

1. < 2;6 years;months & PedsQL ≥ 83
2. < 2;6 years;months & PedsQL < 83
3. ≥ 2;6 years;months & PedsQL ≥ 83
4. ≥ 2;6 years;months & PedsQL < 83

Reasons:

2;6 = median age + possible WPPSI-IV
83 = cut off for potential group of
“children with special health care
needs” in total functioning in PedsQL

Huang et al., 2009

CTIS application	
Application submission	15 May 2024
Feedback (RFI) Part II Germany (Patient information and ICF, qualification documents)	12 Jun – 26 Jul 2024
Feedback (RFI) Part I (protocol documents): need to apply via BfArM and PEI => Withdrawal of CTIS application	Jul 2024
New submission (DK, F, NL, B, D): COGNITO-MB	Planned for April 2025
Submission other EU countries and non CTIS countries (1st major amendment)	After approval of submission, e.g. 8/25

TrluMPh

Prospective, International SIOP-E/PNOC Phase II Trial
for Infants and Young Children with High-Risk
Medulloblastoma

Christelle Dufour

Girish Dhall

Steve Clifford

Gwénaél Le Teuff

On behalf of IOP-E Infant working group and PNOC

TrluMPh: main eligibility criteria for MB cohort

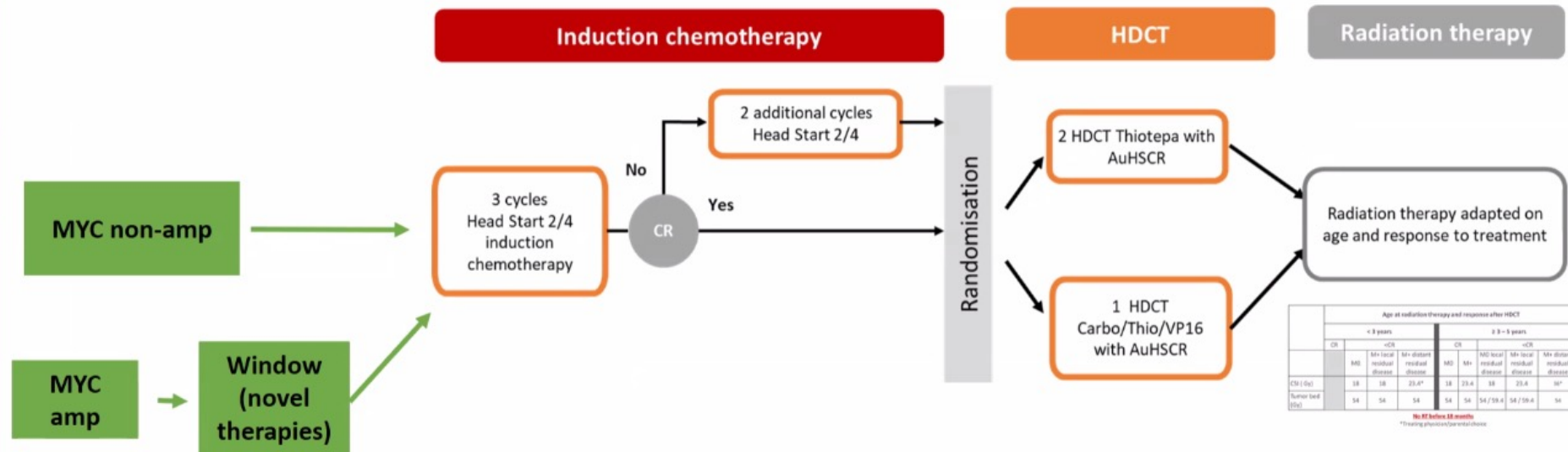
- Age at diagnosis, below 5 (date of diagnosis = primary tumour surgery/biopsy)
- Newly diagnosed non-SHH / non-WNT MB
- **Newly diagnosed metastatic SHH TP53 wild-type MB** **PROPOSAL**
- Submission of high quality biological material to the national biological reference centres, including fresh frozen tumour samples and blood for the molecular assessment of biological markers, is mandatory for definition of subgroup and risk group status.
- Definition of clinical risk group (necessary for stratification at randomisation), by/
 - Central neuroradiological review (cerebral MRI pre-, and early after surgery; spinal MRI)
 - Lumbar CSF
- Pre-operative health-related Quality of Life (QoL) (age-specific PedsQL) available (assessed retrospectively after diagnosis).
- Start of chemotherapy planned no more than 28 days after primary surgery.
- No prior therapy for MB other than surgery.

Stai visualizzando lo schermo di Christelle Dufour REC

Visualizza opzioni



TrluMPH – suggestion?



- Futureproofing
- Include placeholder window to insert novel therapies for VHR disease (slot in when they become available)
- Link to ITCC-MB group

Trlumph : MB cohort



8 to 10 eligible patients per year

11 participating countries
38 to 43 eligible patients per year

The JPEH HGG Study



Protocol Title: A Randomized, Open-Label, Phase 2 Study Evaluating Abemaciclib in Combination With Temozolomide Compared to Temozolomide Monotherapy in Children and Young Adults With Newly Diagnosed High-Grade Glioma Following Radiotherapy

Protocol Number: I3Y-MC-JPEH

Phase of Development: Phase 2

Abemaciclib Compound Overview

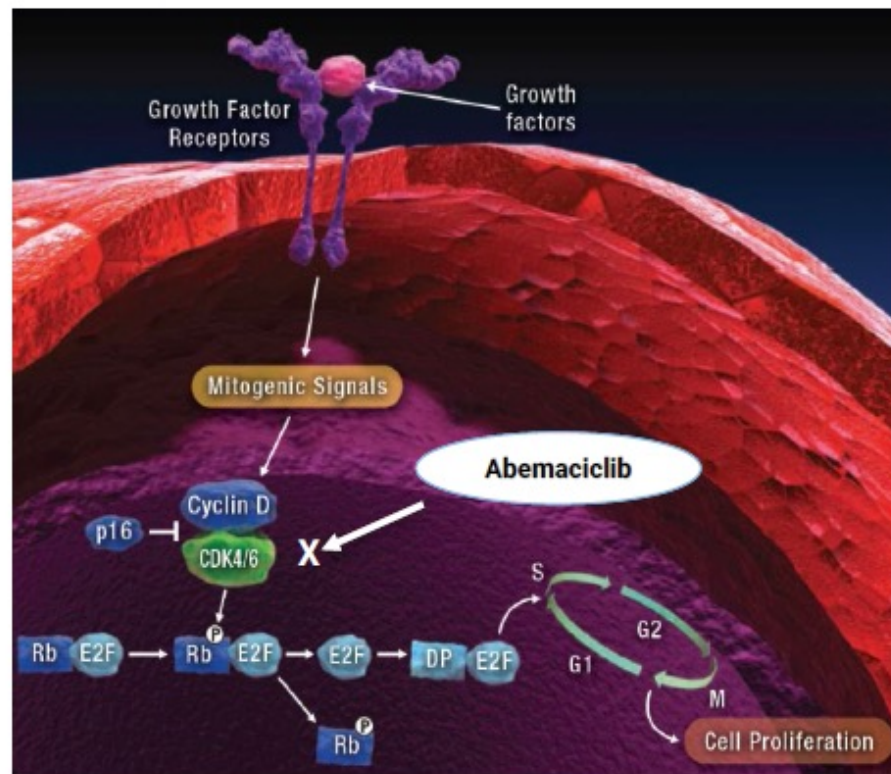
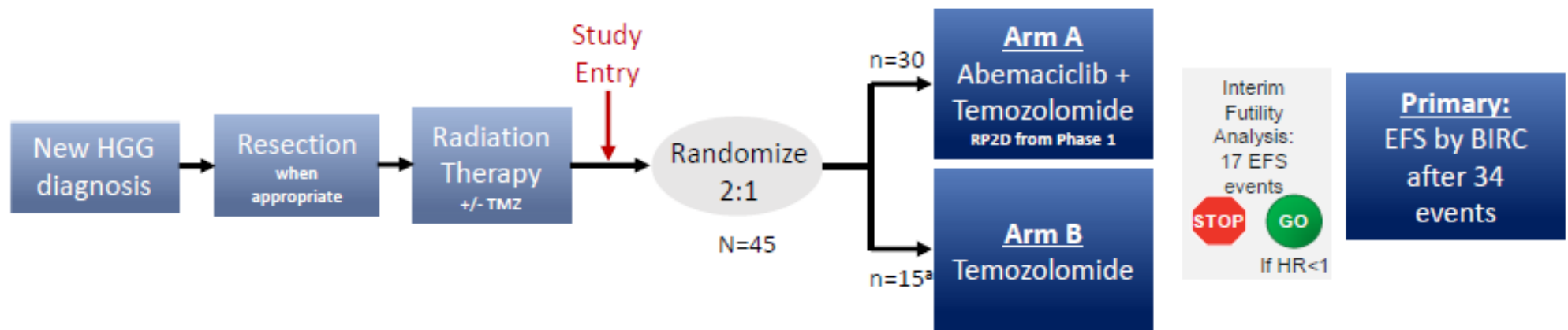


Figure adapted from: www.personalizedmedonc.com/article/abemaciclib-ly2835219-a-dual-inhibitor-of-cdk4-and-cdk6/

Abemaciclib

- Potent CDK4 & 6 inhibitor
- Disrupts the cell cycle
- Single agent activity
- Crosses the BBB
- Greater potency for CDK4 than CDK6 in enzymatic assays potentially leading to less myelotoxicity
- Only CDK4 & 6i dosed on a continuous schedule
- Approved for certain types of HR+, HER2- breast cancer
- Warnings and Precautions
 - Diarrhea
 - Neutropenia
 - Hepatotoxicity
 - ILD/pneumonitis
 - VTE
 - Embryo-fetal toxicity

Study Design



^aBayesian augmented control arm (in addition to the 15 participants enrolled)

Stratification

CDK4/6 pathway alterations (Yes vs No vs Unknown)

Secondary endpoints

EFS by inv. assessment, OS, response, safety, PK, acceptability and palatability of abemaciclib

Centri aperti

- Napoli-Santobono (10/2024)
- Genova-Gaslini (9/2024)
- INT (1/2025)

Prossima apertura

- Roma OPBG e Gemelli
- Padova-IOV
- Torino-Ospedale Regina Margherita

2 pazienti arruolati USA

2 pazienti arruolati Spagna

Chiusura studio: 10/2025



Phase I study of anti-GD2 Chimeric Antigen Receptor-Expressing T cells in pediatric and young adult patients affected by relapsed/refractory central nervous system Tumors

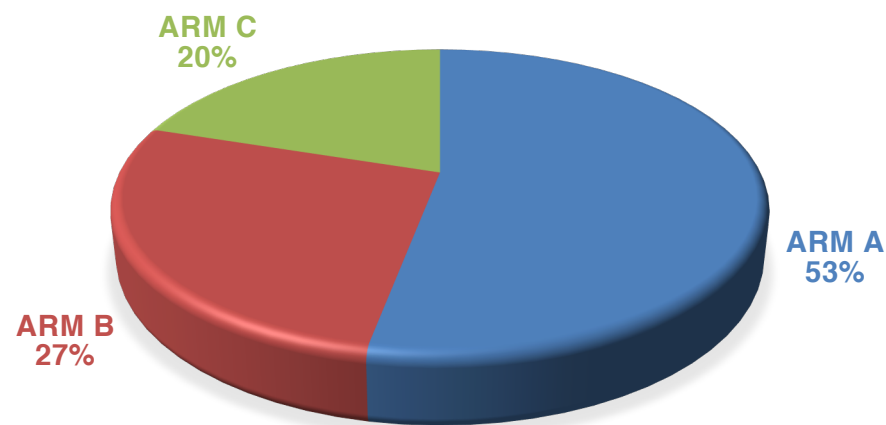
P.I. Prof Franco Locatelli

ClinicalTrials.gov Identifier: NCT05298995

Clinical Trial Design

- Tre braccia di trattamento:
 - **ARM A: MB/altri tumori embrionari**
 - **ARM B: HGG emisferici**
 - **ARM C: HGG talamici, DMG e altri rari tumori del SNC non inclusi nell'arm A e B**
- Dose levels per ogni braccio:
 - DL1: 0.25×10^6 cells/kg di CAR+ T cells
 - DL2: 0.5×10^6 cells/kg di CAR+ T cells
 - **DL3: 1.0×10^6 cells/kg di CAR+ T cells**
 - DL4: 3.0×10^6 cells/kg di CAR+ T cells
 - DL5: 6.0×10^6 cells/kg di CAR+ T cells
- Arruolamento parallelo in sequenza per ciascun braccio: una volta concluso l'arruolamento della coorte di pazienti DL3 del braccio A, in assenza di DLT, sarà attivato un arruolamento parallelo come segue: coorte DL4 di pazienti dell'ARM A e coorte DL3 di pazienti dell'ARM B. La stessa strategia sarà applicata all'ARM C.
- **Si prevede di includere 27 pazienti**, secondo lo schema di escalation della dose 3+3, fino a un massimo di **54 pazienti** (18 pazienti per braccio) arruolati in un periodo di 24 mesi.

- *Data apertura protocollo: 09/11/2023*
- *Arruolamento attuale: 19 pazienti*
- *Pazienti trattati attualmente: 15 pazienti*





GdL – Tumori del Sistema Nervoso Centrale (SNC)

**Studio spontaneo osservazionale retrospettivo sui
Tumori del Sistema Nervoso Centrale
e Studio spontaneo osservazionale prospettico sui
Tumori del Sistema Nervoso Centrale**

VERSIONE 2.2 DEL 28.08.2023

Aggiornamento attivazione Centri per DI-TSNC al 10.03.2025

Numero complessivo Centri previsti: 35

Centri attivi

20 (GE, PV, MI INT, PD, VR, TS, PR, MO, BO, FE, TO, TN, LE,
Roma Gemelli, PA, TA, CT, San Giovanni Rotondo, CA, BA)

Centri con parere favorevole CE *ma per i quali manca accordo di collaborazione*

6 (Aviano, Udine, Roma OPBG, Napoli Pausilipon,
Catanzaro, Reggio Calabria)

Centri in attesa di parere favorevole CE 1 (Perugia)

Centri da presentare al CE

6 (VI, Ancona, Pesaro, Nocera Inferiore, CS, BZ)

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