EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

SPECTA
EORTC

SPECTA platform and downstream projects

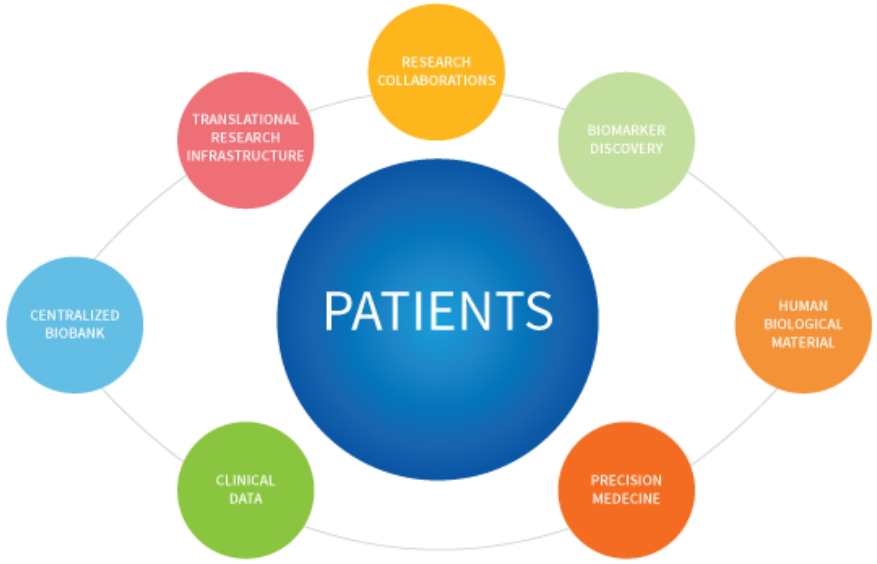
A Non-Interventional International Translational Research Platform of the EORTC

@EORTC

Understanding SPECTA

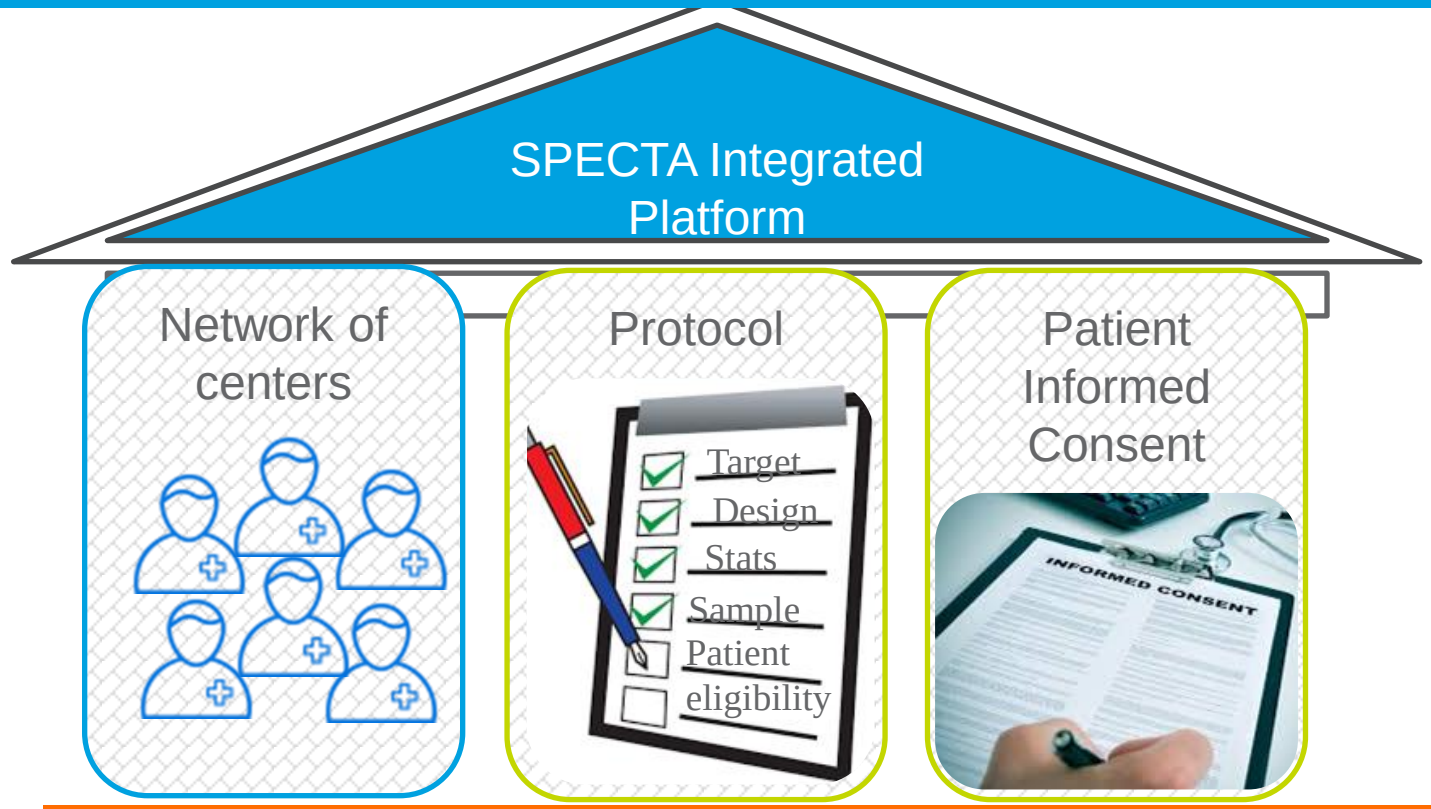
- SPECTA is an infrastructure to reach patients with cancer, treated with standard of care
- It allows the collection of **Human Biological Material,**

together with the collection of **Patient clinical data** (e.g. patient's age, gender, tumor characteristics…) and **imaging data**



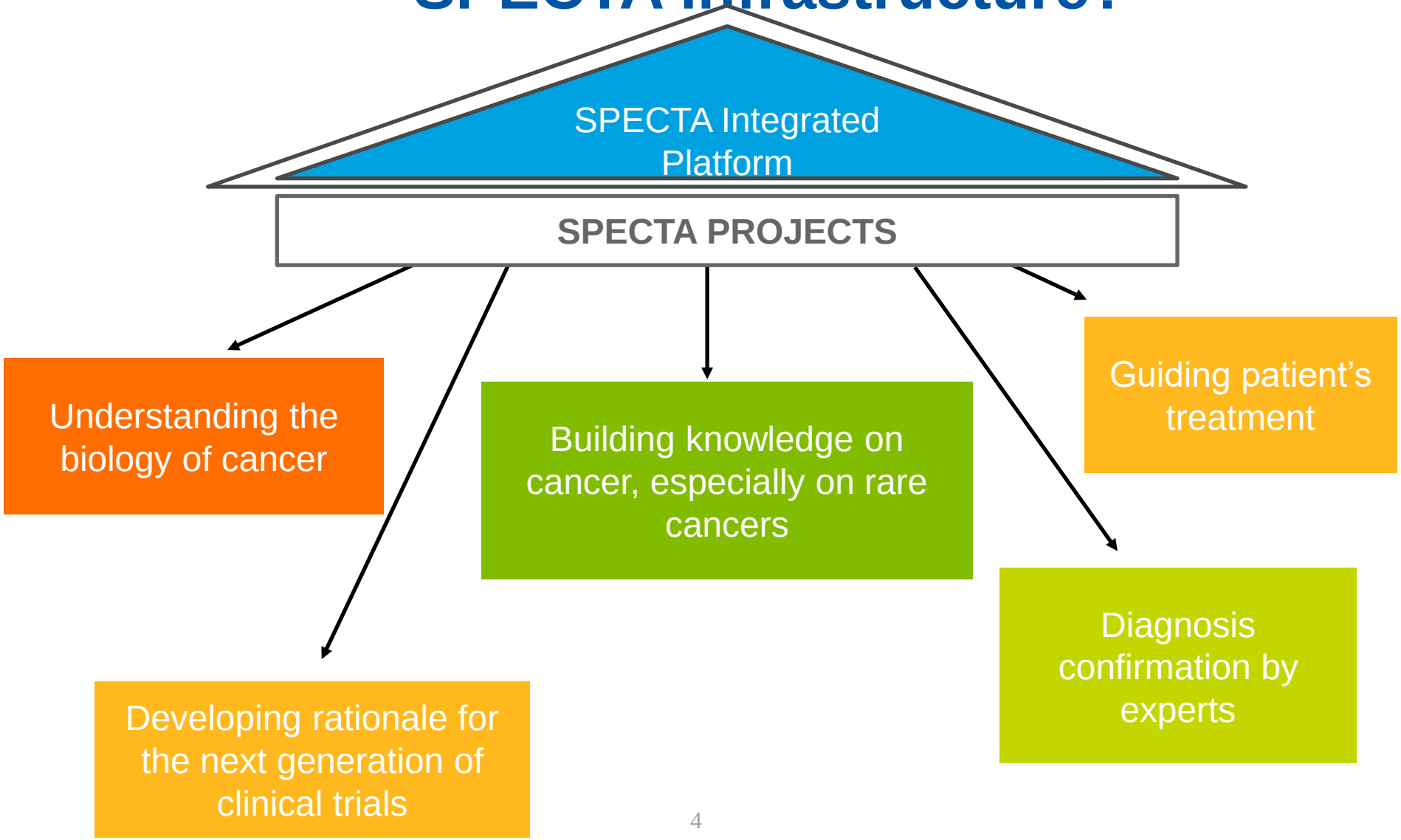
SPECTA - Infrastructure

- Facilitates Cancer patients recruitment
- Enables a rapid access to patient data and samples
- Set-up quality workflow for sample collection and molecular analysis



One authorization in 1553-SPECTA to recruit in SPECTA projects

What are the goals of the projects using the SPECTA infrastructure?

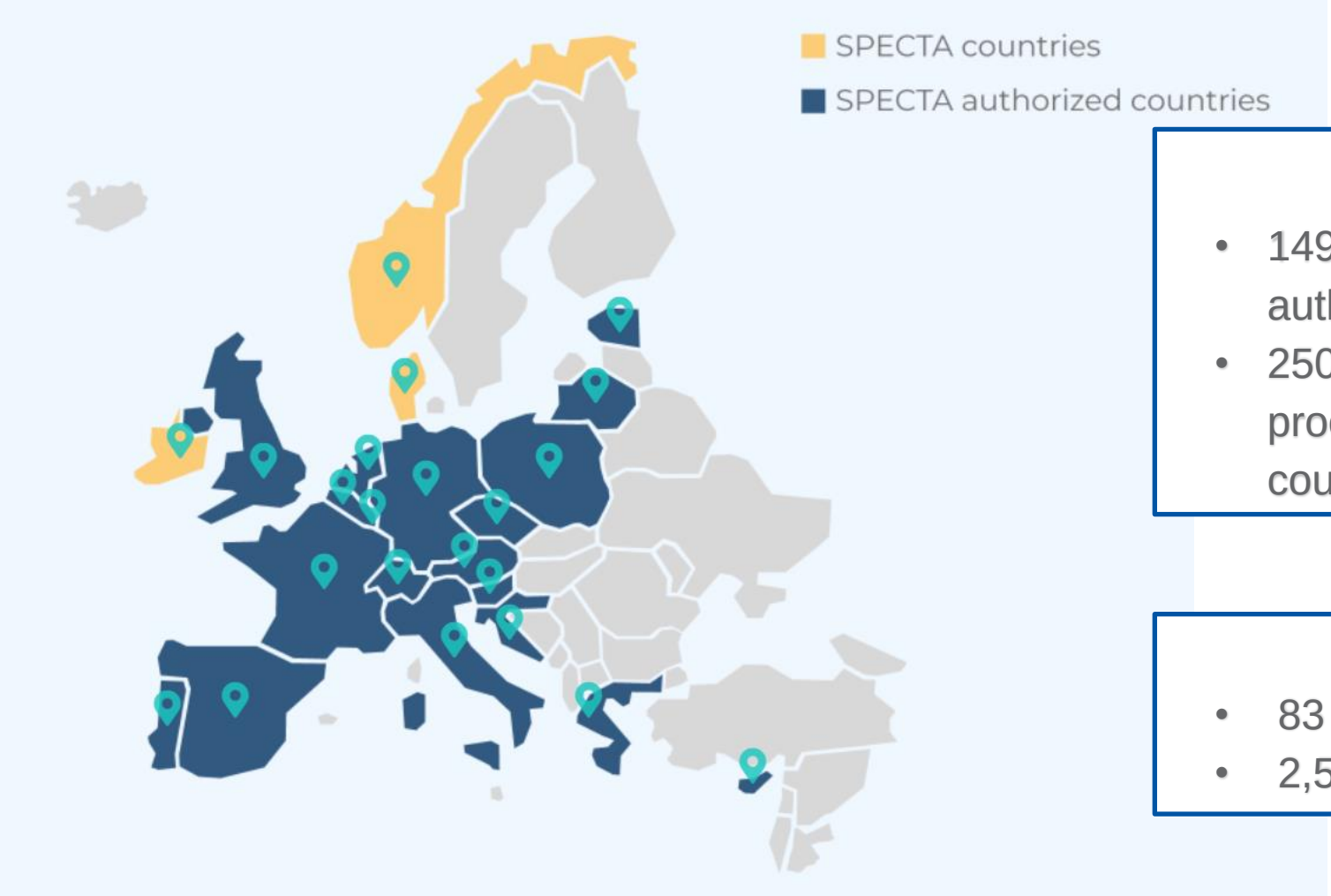


Downstream Projects

SPECTA
One protocol, one informed consent, many projects

Analysis	Conduct			Dev/Activ
SPECTA lung n=528 All thoracic malignancies Targeted NGS	**IMMUcan** N=3000 NSCLC, CRC, TNBC, HER-2 BC, HNSCC, RCC	**Arcagen** N=1000 Rare cancers	**Bioradon** N=975 NSCLC	**MRD** N=250 per cohort
SPECTAcolor n=835 Metastatic CRC	WES, RNAseq & IF, IMC	NGS panel (FMI)	Radon exposure	WES and regular blood MRD assay
AYA N=98 HGG and sarcoma WES, RNAseq & Methylation array				

SPECTA - Current Operational Status



SPECTA Activation process (*):

- 149 investigators from 19 countries are currently authorized to recruit
- 250 investigators are authorized or in the process of joining, from 180 centers and 21 countries

Recruitment (*)

- 83 recruiters from 67 different centers
- 2,500 patients recruited in 3 years

* Cut-Off date: 16/09/2022

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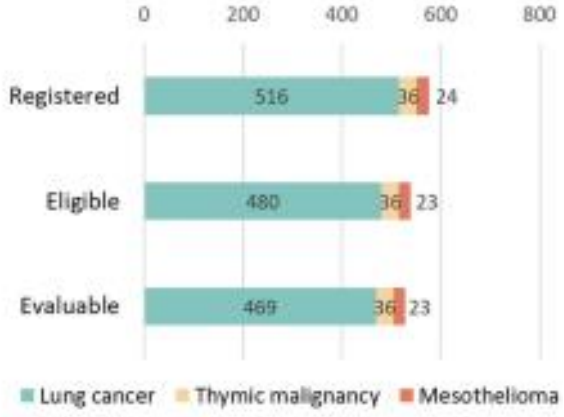
SPECTAlung

a)

Recruitment per country

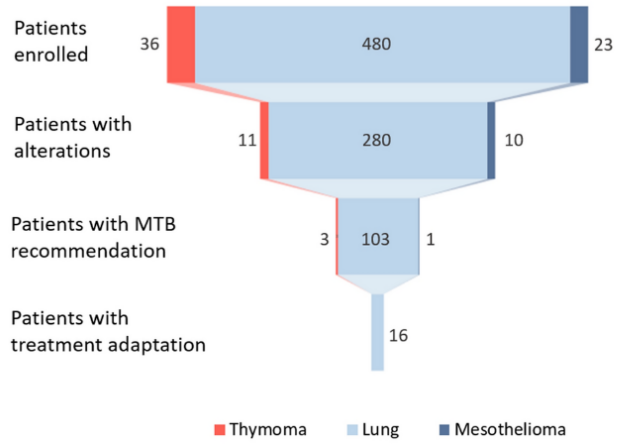
b)

Registered and evaluable patients



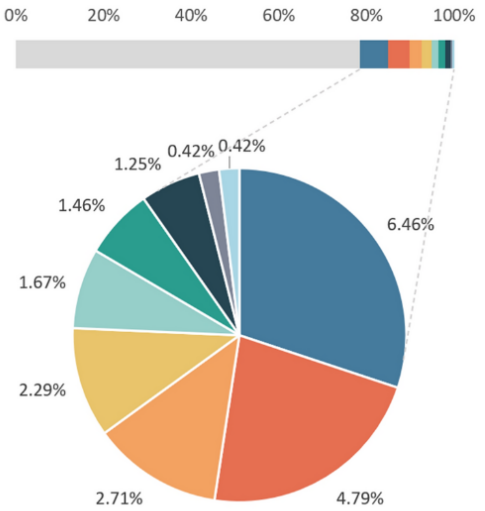
a)

Treatment recommendations overview



b)

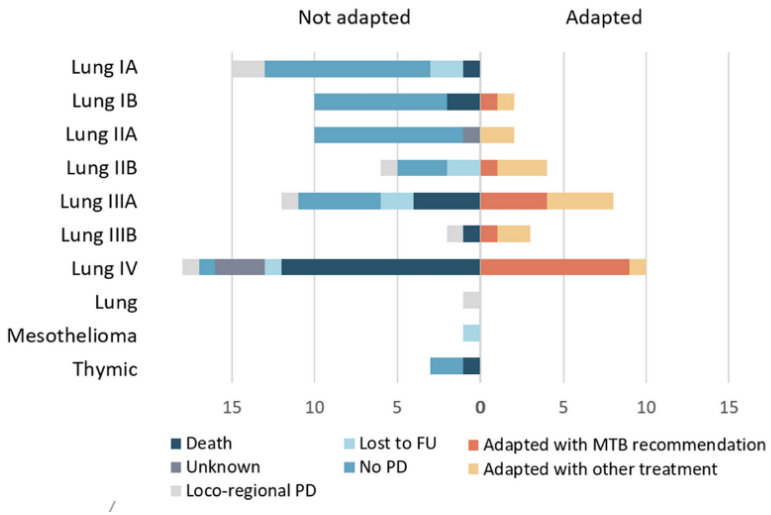
Treatment recommendations for lung patients



- EGFR mutation
- RET/ALK/ROS1 fusions + MET exon 14 skipping
- HER2 amplification
- Others
- FGFR mutations/amplificaton
- IO
- PI3K/mTOR/AKT mutation
- ATM alteration
- CDK4/6 amplification
- No treatment recommendation

c)

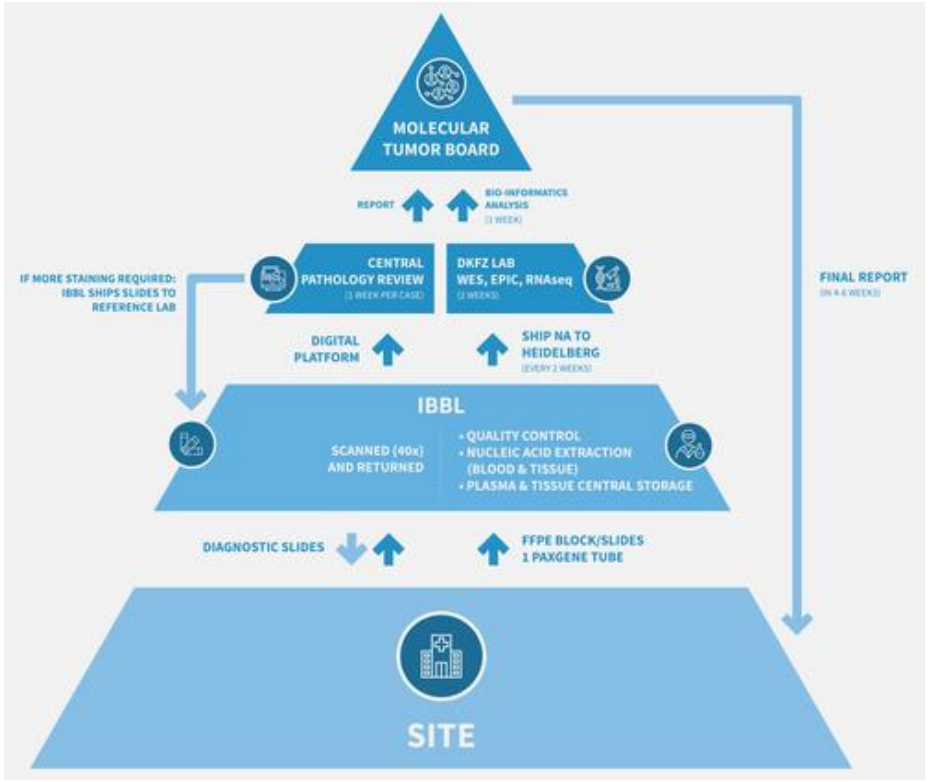
Treatment adaptations



Morfouace, et al., Sci Report, 2022

RP-1759 - AYA

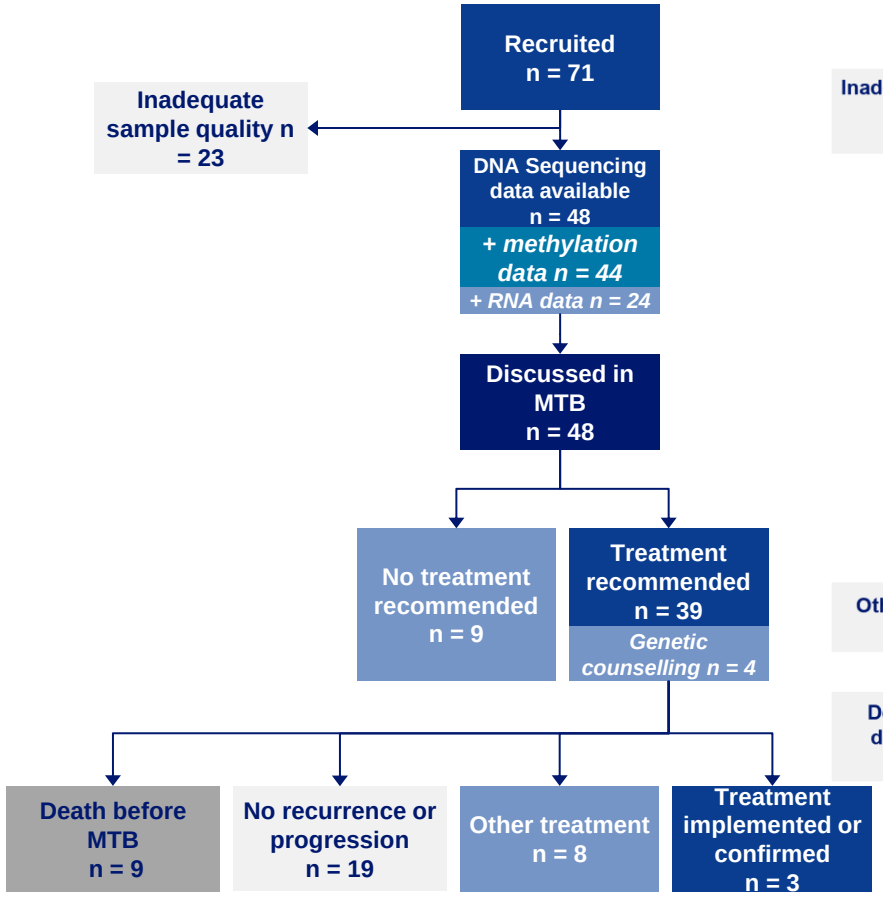
Workflow: from clinics to molecular tumor board



deRojas, et al., IJC, 2019

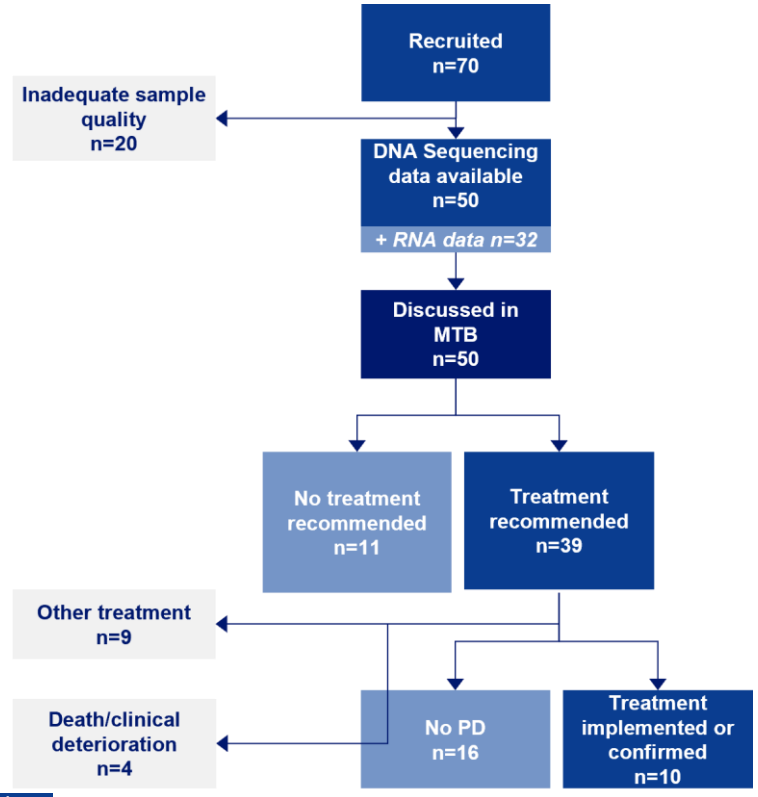
Age:12 and 29 years old
Diagnosis: high grade glioma and sarcoma
Primary or Recurrence

Sarcoma cohort



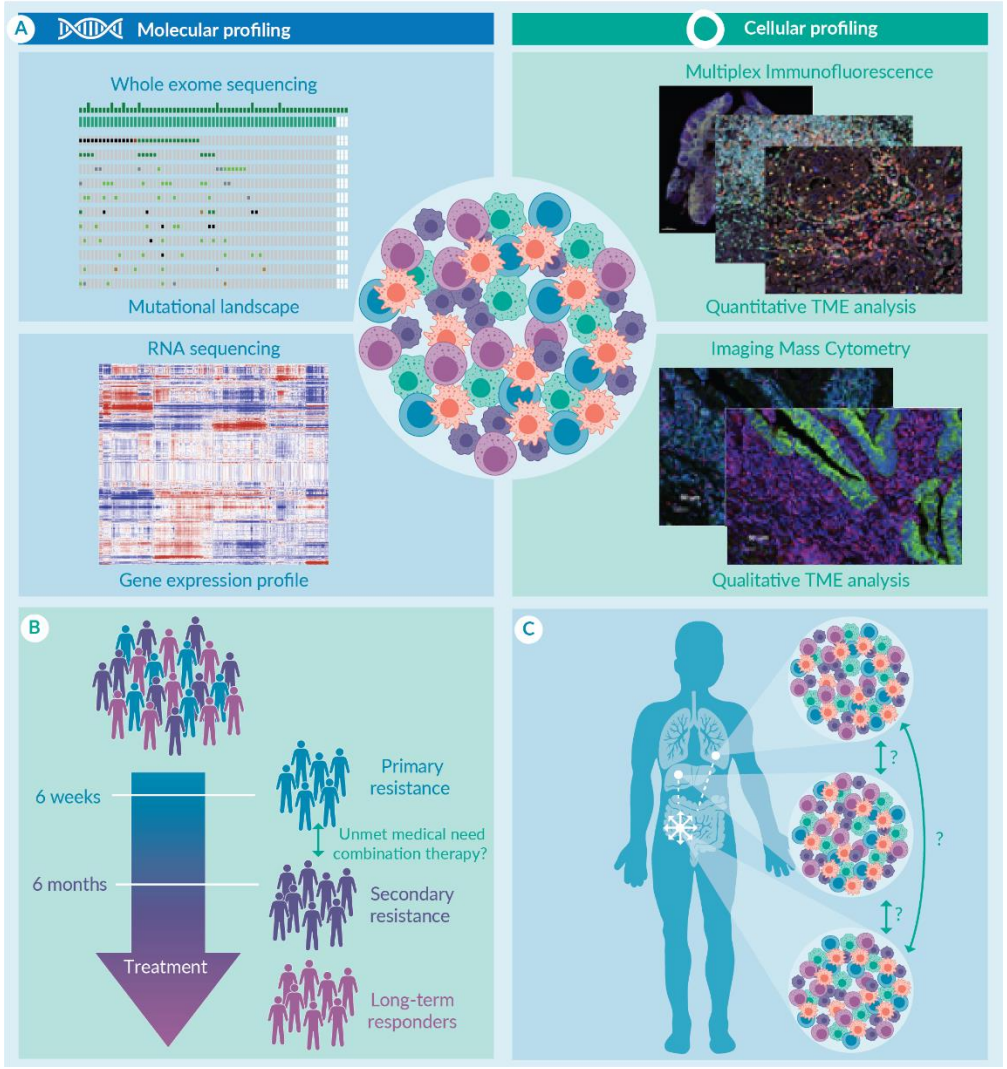
Morfouace, et al., submitted

CNS cohort



manuscript in preparation

RP-1828 - IMMUcan



Molecular report (4-6 weeks)

Monthly Molecular Tumor Board

32 lung MTB
2 H&N MTB
1st breast MTB in October

Hong, et al., Immuno-Oncol Insights, 2021

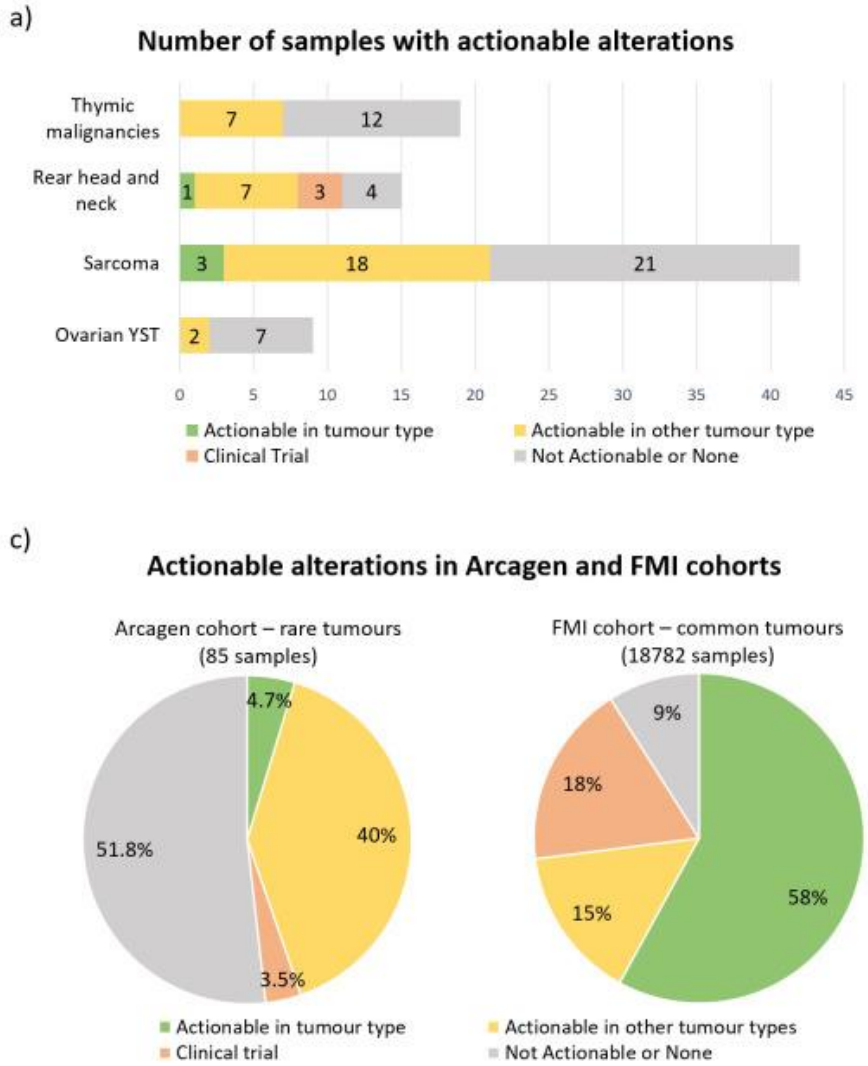
RP-1843 - Arcagen

NGS panel analysis

Molecular report
(4-6 weeks)

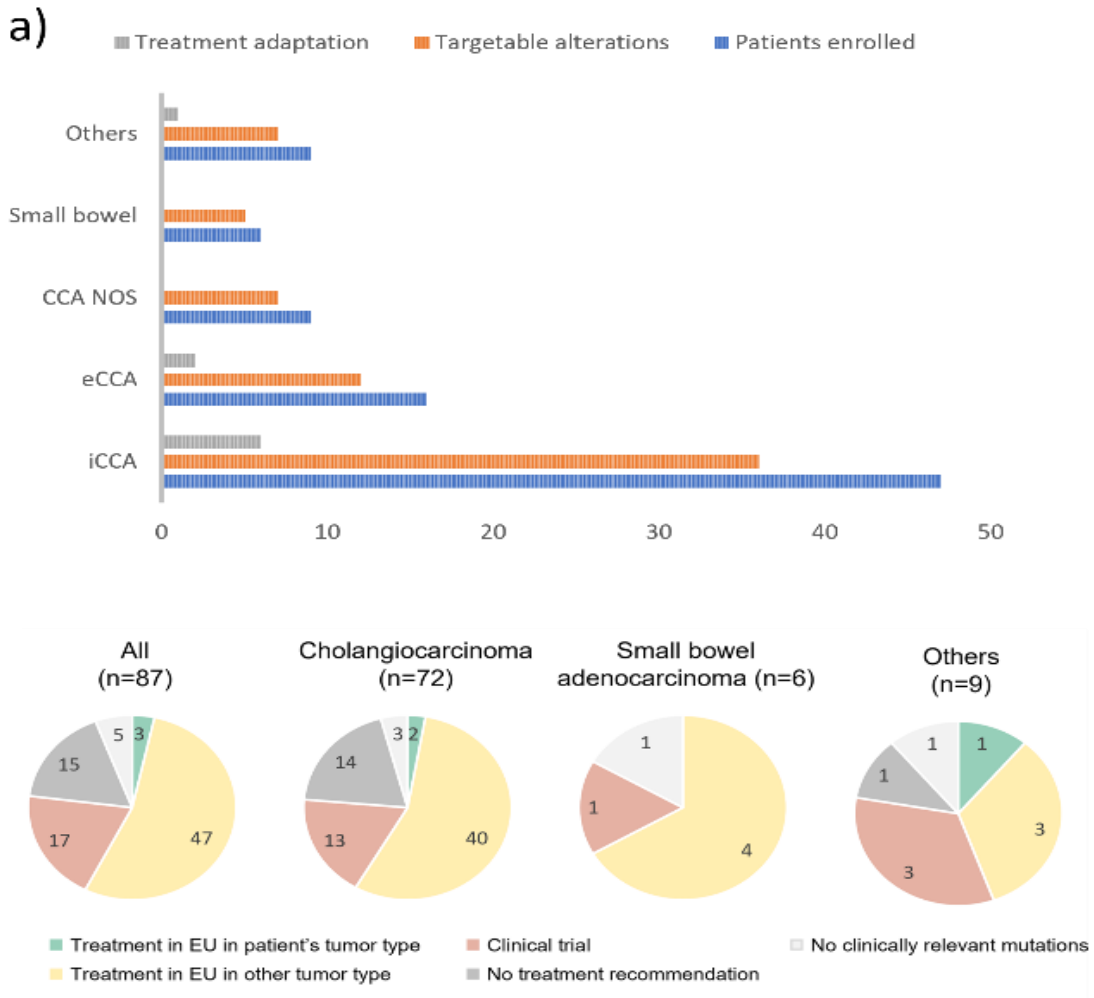
RP-1843 - Arcagen

Retrospective analysis



Morfouace, et al., ESMO Open, 2020

Prospective analysis – Domain 5 (GI)



Lamarca, Morfouace, et al., Annals of Oncology, 2022

RP-1920 - BioRadon

EORTC: BioRadon – Cohorts and clinical data collection

Patient cohorts

NSCLC patients, DRIVER GROUPS

- Group A: mutation group

EGFR, BRAFV600E, MET, HER2 mutations

- Group B: fusion group

ALK, ROS1, RET, NTRK1/2/3 fusions

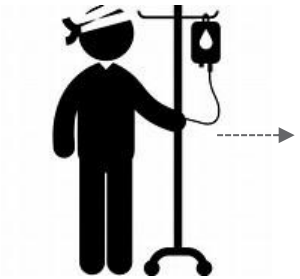
NSCLC patients, CONTROL GROUP

- ***Group C: Control group***

No EGFR, BRAF600E mutation nor ALK or ROS1 fusion

N= 325 per group

When eligible



Clinical data collection in SPECTA

Screening

- Demographic data: age, sex
- Medical history including exposure to cancer-specific risk factors (smoking, alcohol abuse, ...)
- Family history of cancer

Assessments around time of study entry

- WHO performance status
- Vital signs (height, weight, ...)
- Basic lab assessment, if available

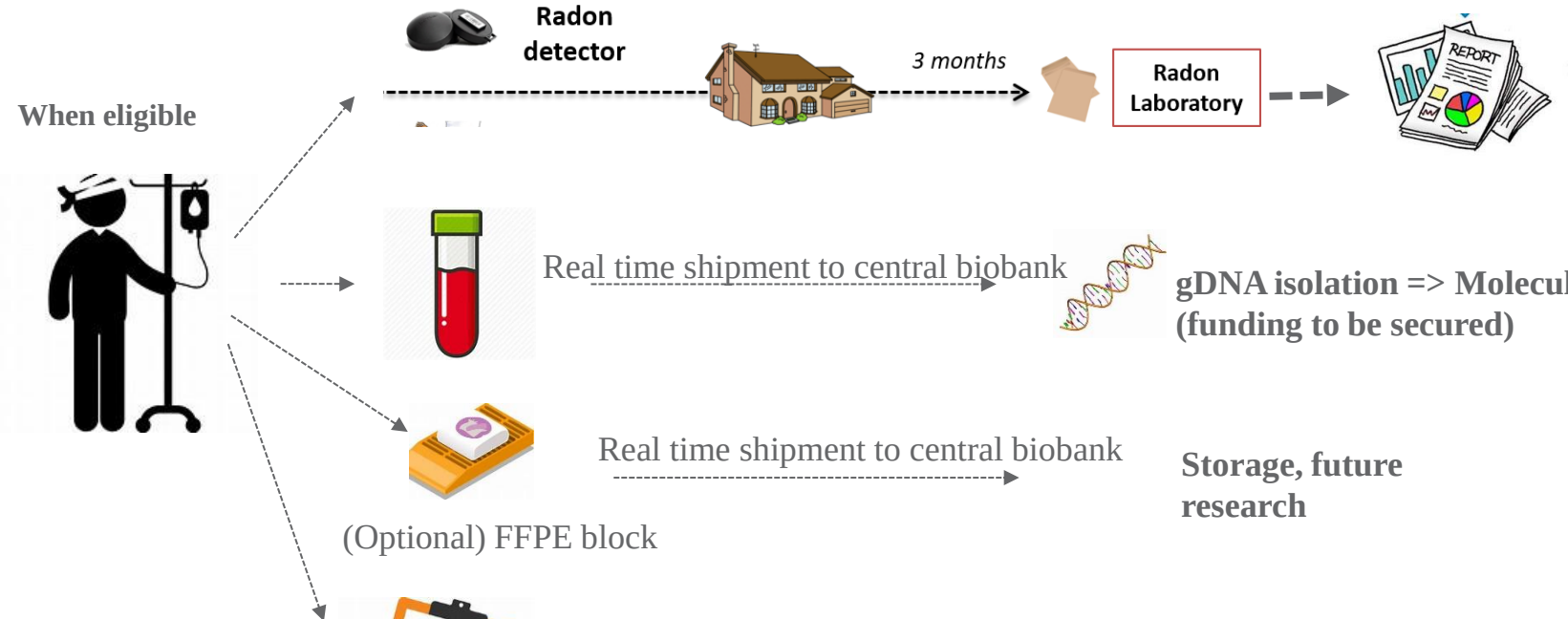
Primary disease

- Date of diagnosis, topography, histology, common pathological information, prognostic factors, staging according to tumor type (based on AJCC latest recommendations)
- Locally performed tumor biomarker analysis results if available

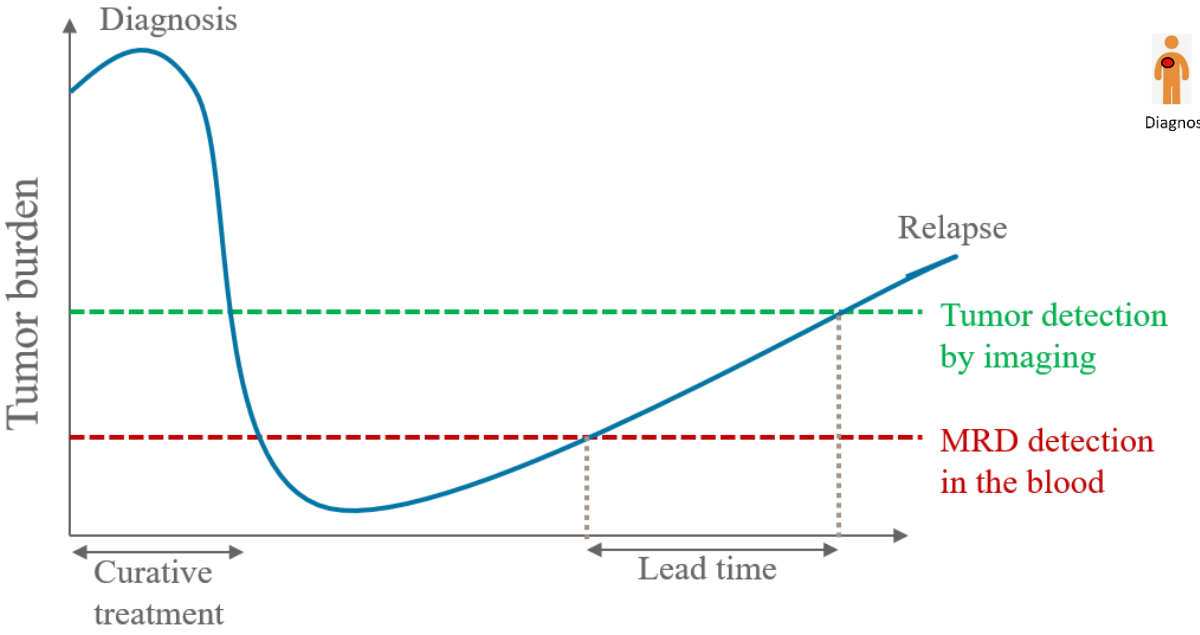
Treatments and progression (follow-up every 3-6 months)

RP-1920 - BioRadon

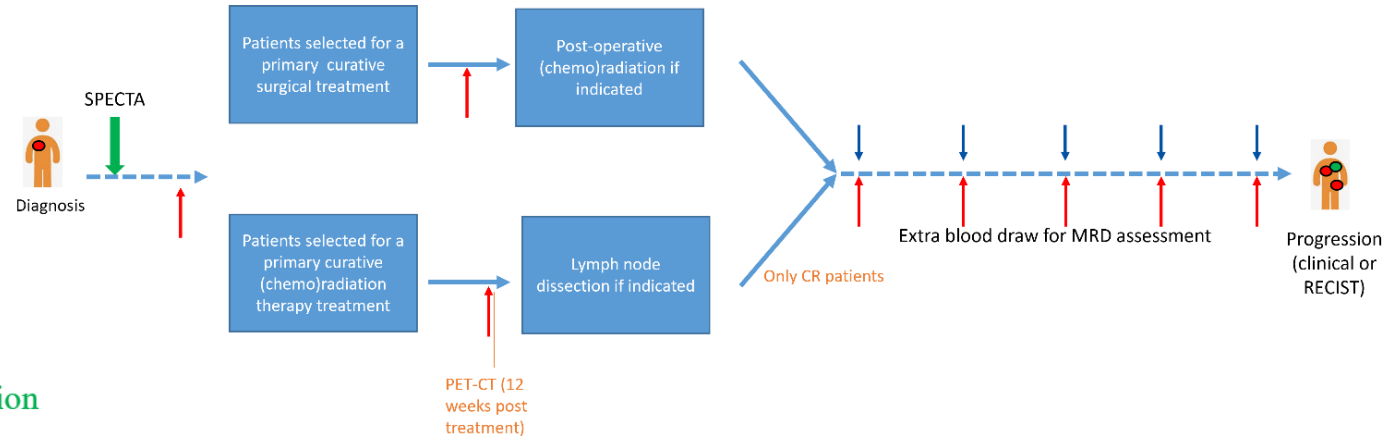
EORTC: BioRadon – HBM and patient questionnaire



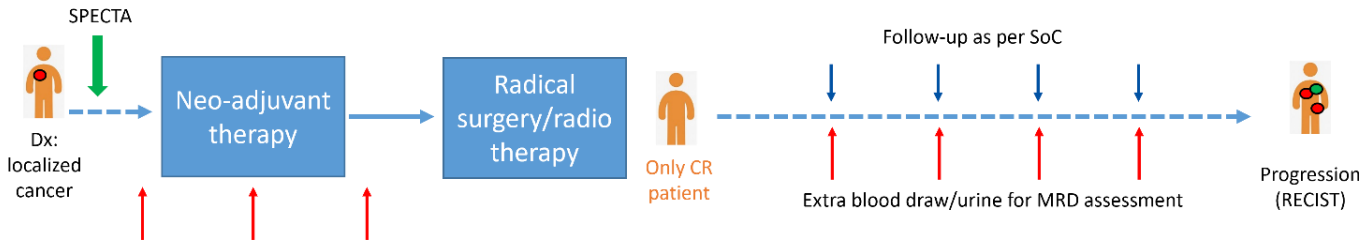
RP-2148 MRD



HNSCC cohort



Bladder cohort



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EORTC runs separately “Basket and Umbrella” studies

Interventional clinical trials

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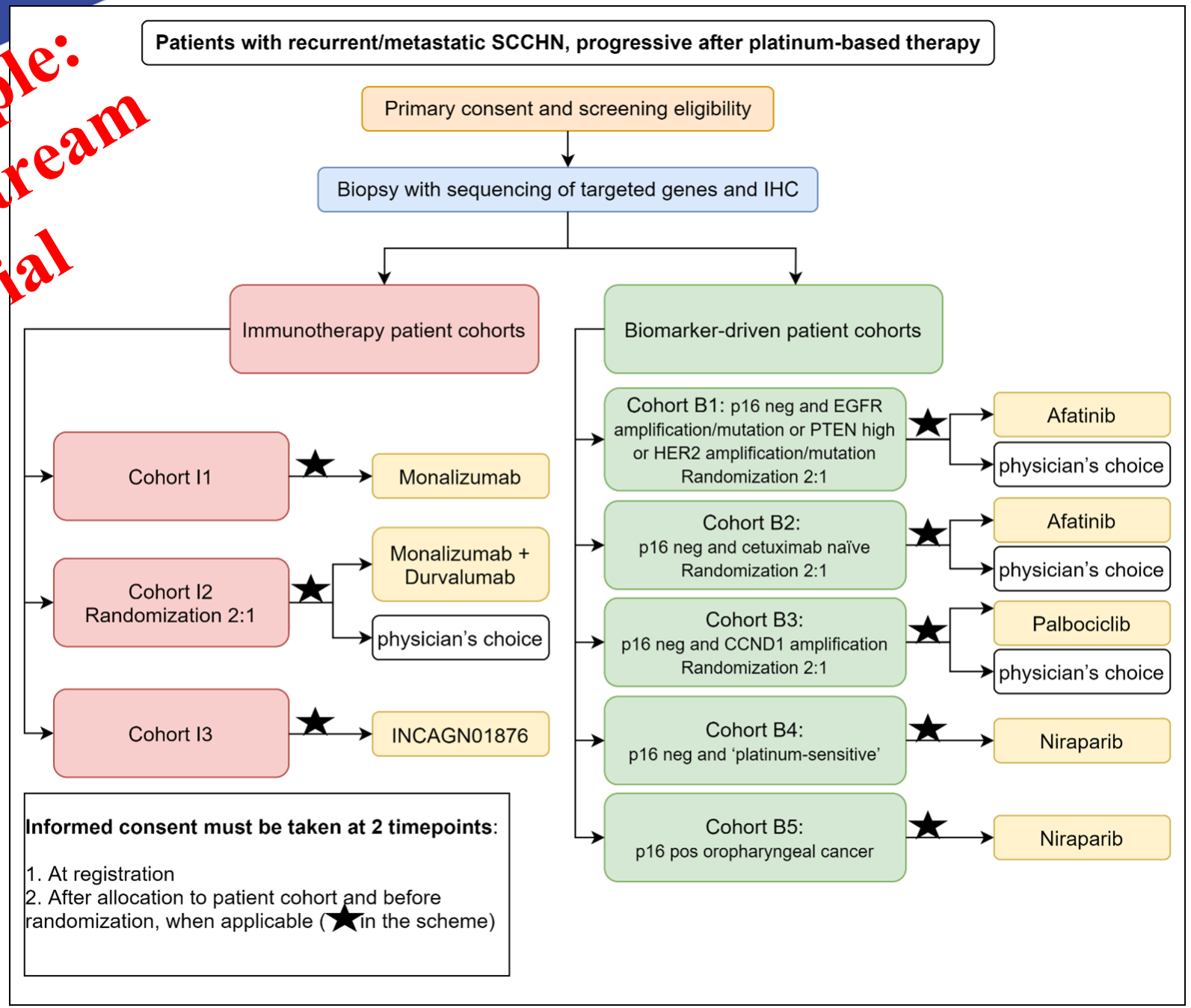
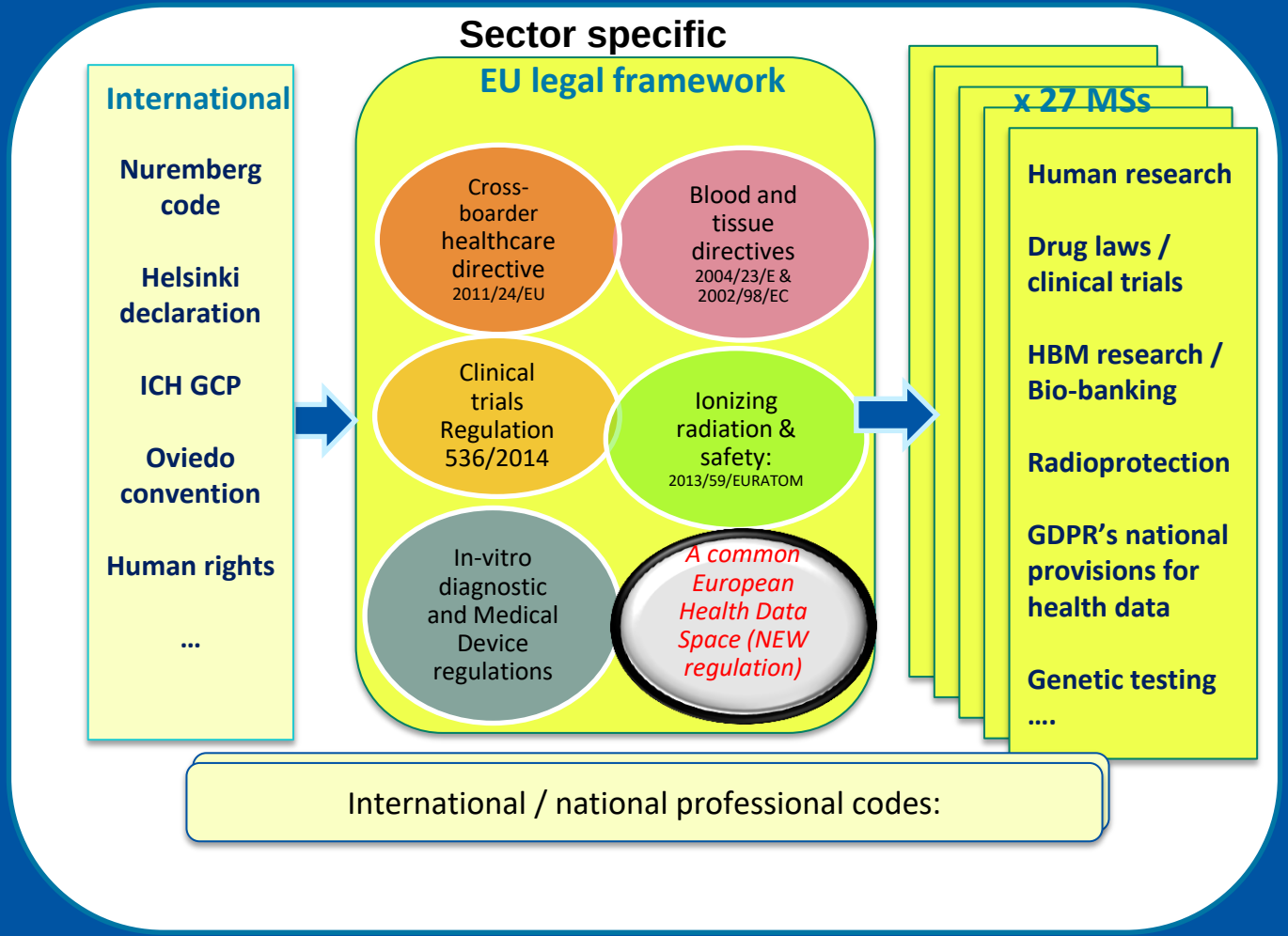
An example: The Upstream Trial



Current clinical research framework in EU



Applicable to all sectors:

- GDPR
- ePrivacy Directive (NEW)
- Data Governance Act (NEW proposal)
- AI framework (NEW proposal)
- Cloud code of conduct
- …

Key learnings-Learning the hard way….sometimes

- The EU regulatory framework is not necessarily optimal for complex trials
- The evolution of the regulatory framework needs a careful impact assessment (CTR, MRD, IVDR, GDPR), Research Use Only / Secondary use of HBM
- Strategy non-interventional vs interventional to be assessed
- Complex multi-arm interventional trials are not necessarily agile i.e. amendment process
- International translational and clinical research infrastructure are costly to maintain
- Quality Assurance programmes have a structuring effects on participating sites
- International multidisciplinary Molecular Tumor Board are critical to improve new knowledge uptake
- Need for pan European rare cancer screening programs as demonstrated by Arcagen (1,000 pts/3y)
- The capacity of these new programs in substantially changing practice needs longer term evaluation