Swiss Personalized Oncology

2nd monitoring meeting | 19.09.2023

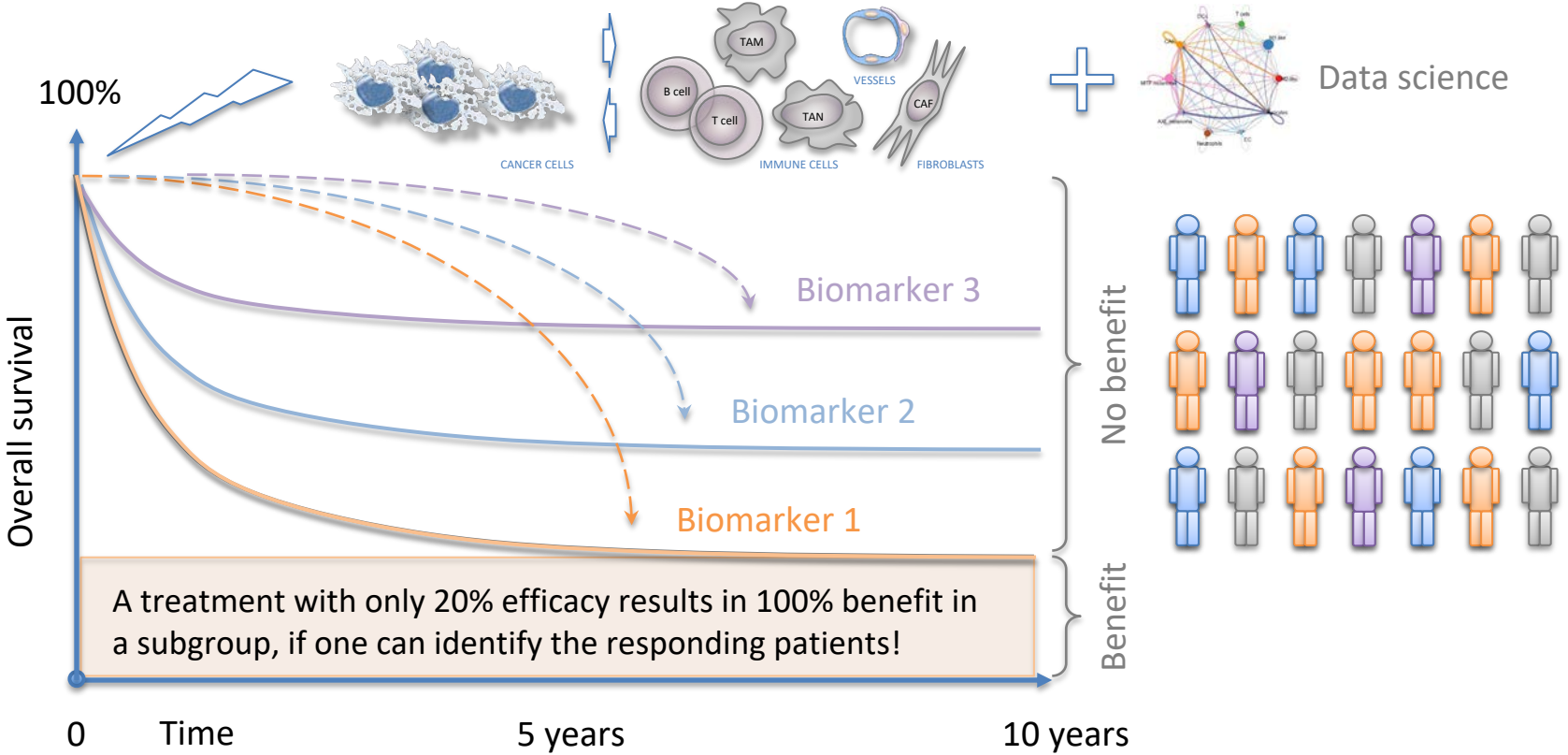
Swiss Personalized Oncology
National Data Stream

Prof. Olivier Michielin, MS, MD-PhD
Prof. Bernd Bodenmiller, PhD

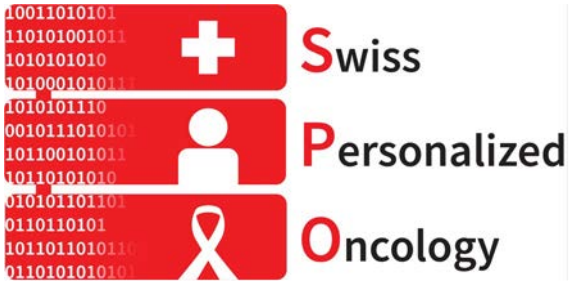
Swiss Personalized Health Network

Strategic Focus Area
Personalized Health and Related Technologies

Why?


100%
CANCER CELLS
TAM
B cell
T cell
TAN
VESSELS
CAF
IMMUNE CELLS
FIBROBLASTS
Data science
Biomarker 3
Biomarker 2
Biomarker 1
No benefit
Benefit
Overall survival
A treatment with only 20% efficacy results in 100% benefit in a subgroup, if one can identify the responding patients!
0
Time
5 years
10 years

Goals



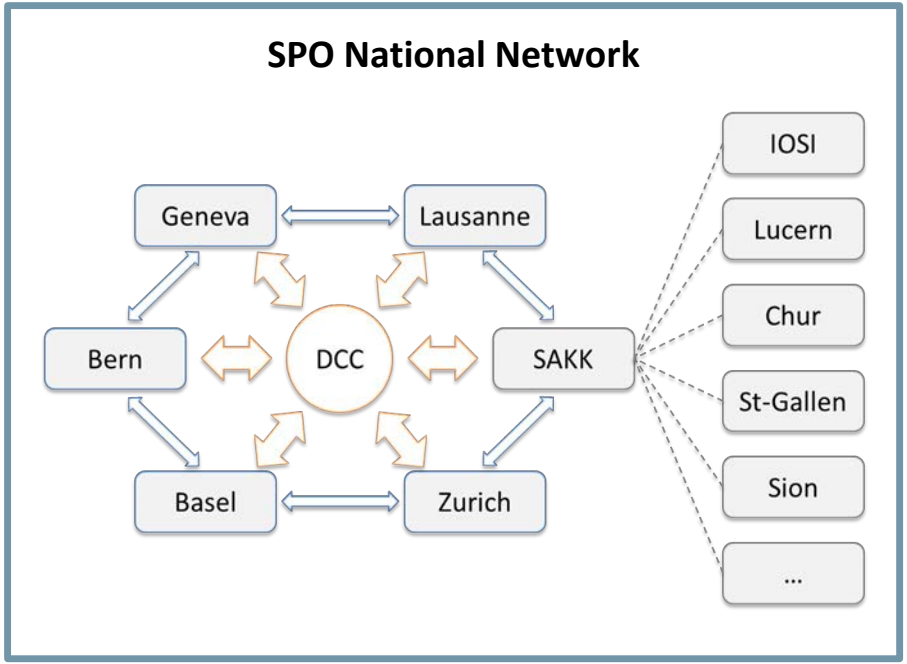
The Swiss Personalized Oncology National Data Stream aims at bringing precision oncology in the form of FAIR clinical and advanced omics data to molecular tumor boards at the local and national level, providing unprecedented decision support for personalized therapies.

Goals

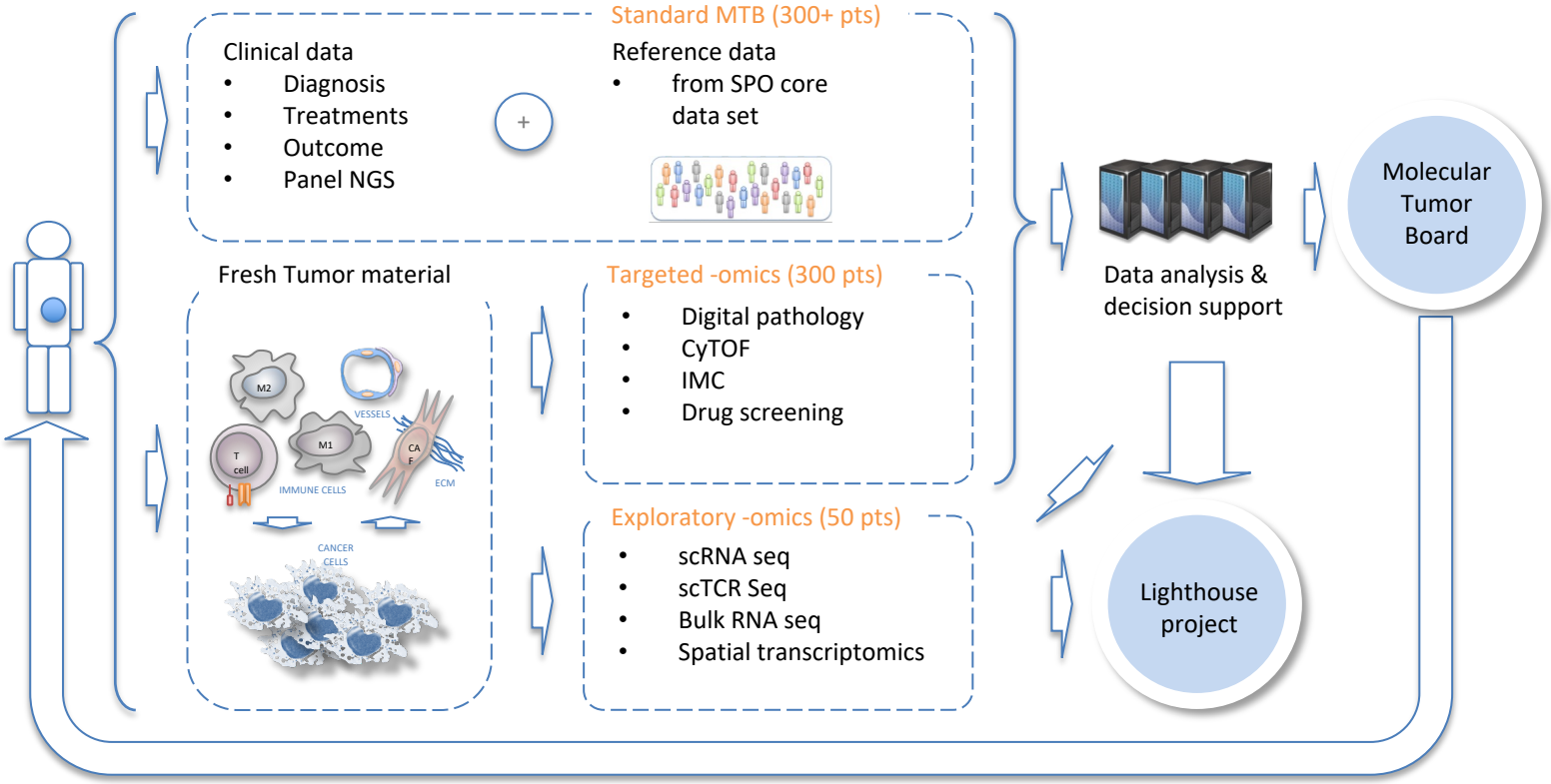
Assemble 4 cohorts of specific cancer types treated with immuno-oncology (IO) therapies within the SPO national network to:

- Create a direct link to patient care, allowing new treatment opportunities for patients who have escaped standard of care therapies or for whom several standard of care options exist without a rationale for selection.

- Identify the mechanisms of primary and acquired immunotherapy resistance within and between tumors with different immune-reactivities (Lighthouse project).



How?


Standard MTB (300+ pts)
Clinical data
• Diagnosis
• Treatments
• Outcome
• Panel NGS
+
Reference data
• from SPO core data set
Fresh Tumor material
M2
VESSELS
T cell
M1
CA F
ECM
IMMUNE CELLS
CANCER CELLS
Targeted -omics (300 pts)
• Digital pathology
• CyTOF
• IMC
• Drug screening
Exploratory -omics (50 pts)
• scRNA seq
• scTCR Seq
• Bulk RNA seq
• Spatial transcriptomics
Data analysis & decision support
Molecular Tumor Board
Lighthouse project
Innovative therapeutic options

SPO-NDS Cohorts

Melanoma: Patients who have failed PD-1 adjuvant therapy and who are candidates for first line systemic treatments (200 / year).

Non-small cell lung cancer: Metastatic squamous NSCLC or non-oncogene-driven non-squamous NSCLC patients from the second line (300 / year).

Colorectal cancer: Microsatellite-instable CRC (40 / year) and microsatellite-stable CRC (200 / year) from the second line.

Breast cancer: Advance triple negative breast cancer (200 / year).

Major milestones

Consortium collaboration contract (CA)

- **Negotiations began summer 2022 and contract was fully signed in July 2023.**
- Parties: CHUV, HUG, INSEL, USB, USZ, KSBL, UniGE, UniBe, UniBas, UZH, UniL, HES-SO, SAKK, EPFL and ETHZ.
- Includes as well: Data Transfer and Use Agreement (DTUA), Data Transfer, Processing Agreement (DTPA), Material Transfer Agreement (MTA template).

Ethics Protocol

- **Resubmission approved on August 2023 after CA finalization.**
- Patient recruitment allowed only after ethics approval.

Thanks to the legal departments at the 15 sites and especial thanks to the ELSI help desk at SIB: Julia Maurer, Mathilde Heusghem and Frederic Erard for their support on all CA aspects.

Governance

Olivier Michielin

Bernd Bodenmiller

Andreas Wicki

Executive Board:

One representative of each consortium party
Executive board meetings every three months
Operational core team meeting every other week

Scientific Board:

Investigators involved in the Project and selected experts in the relevant fields.
Patient advocates
Scientific board meetings every three months
Operational omics technologies team meeting every other week
Monthly touch base meeting with patient advocates

Clinical experts
Omics Experts
Data scientist

SPO-NDS Work packages

WP1	Consolidation and expansion of SPO core dataset in all 5 University Hospitals and selected participating non-university hospitals
WP2	Standardization, management, and organization of multi-dimensional data
WP3	Adaptation of TuPro processes for a national molecular tumor board and molecular tumor boards in university hospitals
WP4	Comparative tumor atlas of patients with different levels of immuno-responsiveness (Lighthouse research project)

Main objectives of Data and Devs teams

WP1: Assemble and format clinical data for the retrospective and prospective SPO cohorts

- **Milestone 1.1.** Data stream implementation for SPO core dataset
- **Milestone 1.3.** Text mining tools
- **Milestone 1.4.** Interoperability with SCORED

WP2: Setup the data management system

- **Milestone 2.1.** Setup of Research Data Management System (RDMS)
- **Milestone 2.3-2.6** Onboarding of data generating facilities/labs

WP3: Setup of reporting system for molecular tumor boards

- **Milestone 3.1.** Setup of the national tumor board web-application
- **Milestone 3.2**. Design and implementation of reports for hospital-internal use

Chairs: N. Toussaint & S. Pradervand

SPO-NDS data set

External Ontologies

NCI Thesaurus
OncoTree
ICD-O
SNOMED-CT

Structured clinical routine and admin

Demographic*
Body Height/Weight
Consent
Administrative case
FOPH Diagnosis
Lab Test/Result
Drug Prescription
Drug Administration Event
FOPH Procedure
Radiotherapy Procedure
Survival Status

Pathology

Somatic Variant Finding
Molecular Test
Tumor Marker

Omics metadata

Tumor sample
Omics Assay
Sample Preparation
Data Generation
Data Processing
SOP

Curated data from free text

Oncology Diagnosis*
TNM Classification*
Tumor Stage* / Grade
Metastasis Finding
Oncology Surgery
Line of Systemic Therapy*
Oncology Treatment Assessment*
Simple Score (ECOG)*

- Concepts from SPHN 2023.2 dataset are in black
- New and modified concepts are in red
- A subset of the data will be part of the molecular tumor board report (*)
- SAKK SCORED data were mapped to the SPO-NDS data set

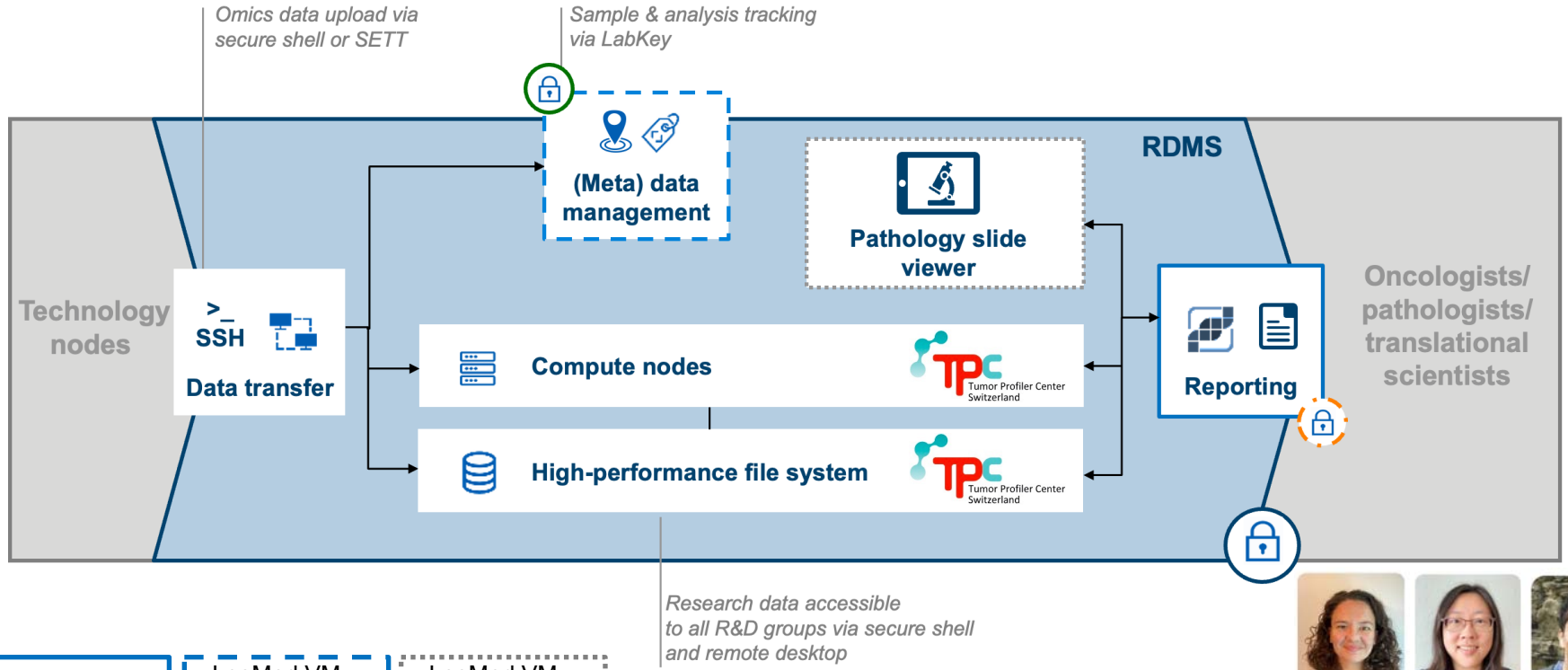
Data collection

- Gap analysis to identify data not yet in the CDW
- Proposed solutions for missing data :

CHUV	In-house data curation tools, REDCap forms
HUG Hôpitaux Universitaires Genève	Molecular TB forms, in-house enrichment pipeline
INSELSPITAL UNIVERSITÄTSSPITAL BERN HÔPITAL UNIVERSITAIRE DE BERNE	Onkostar
Universitätsspital Basel	REDCap forms, pathology data in CDW
USZ Universitäts Spital Zürich	Onkostar, PathoPro

- Interoperability with SCORED SAKK Server and SPHN connector are being set-up

WP2 Standardization, management, and organization of multi-dimensional data

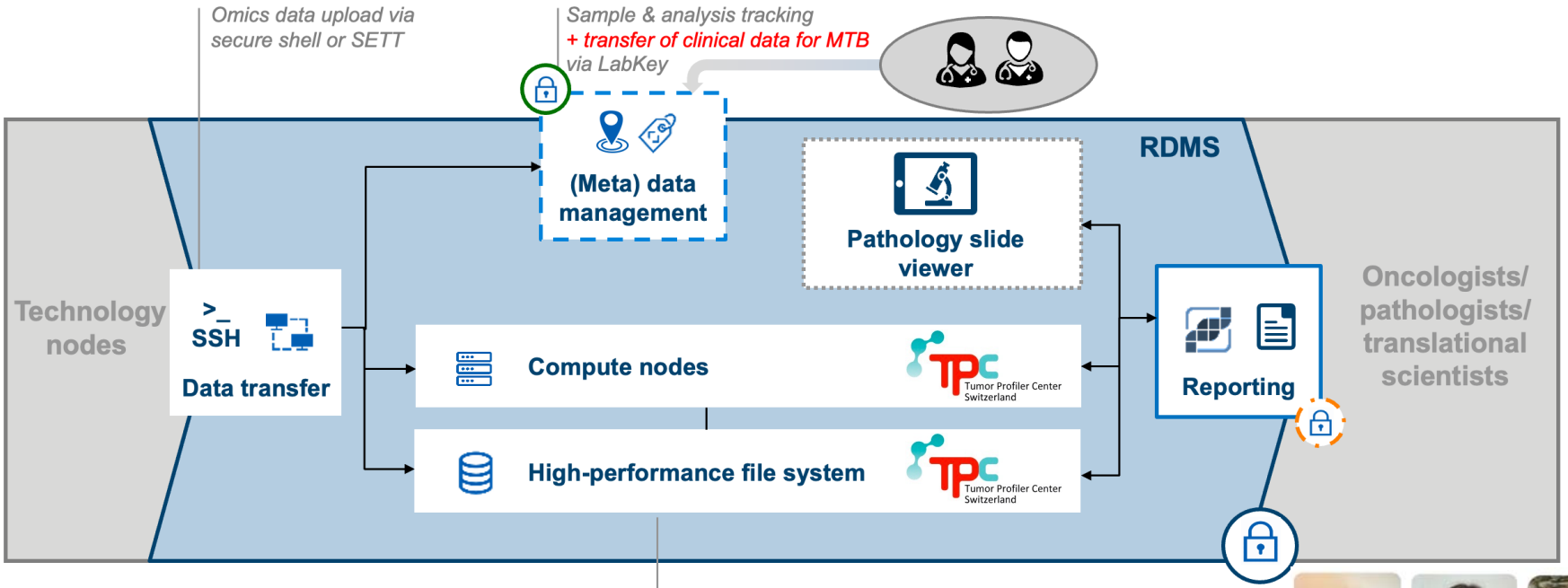


Natalia Chicherova

Shuqing Yu

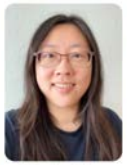

Vipin Sreedharan

WP2 Standardization, management, and organization of multi-dimensional data

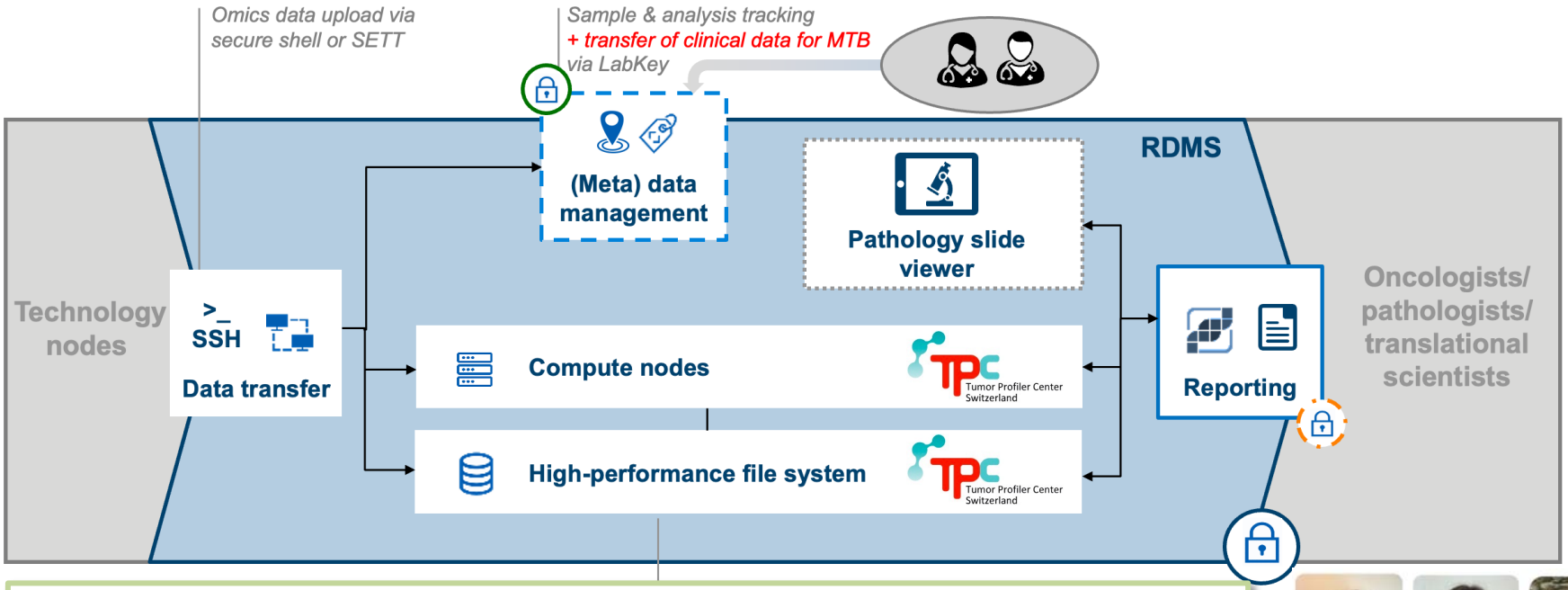


LeoMed VM | LeoMed VM – Outward-facing | LeoMed VM – planned


Natalia Chicherova


Shuqing Yu


Vipin Sreedharan



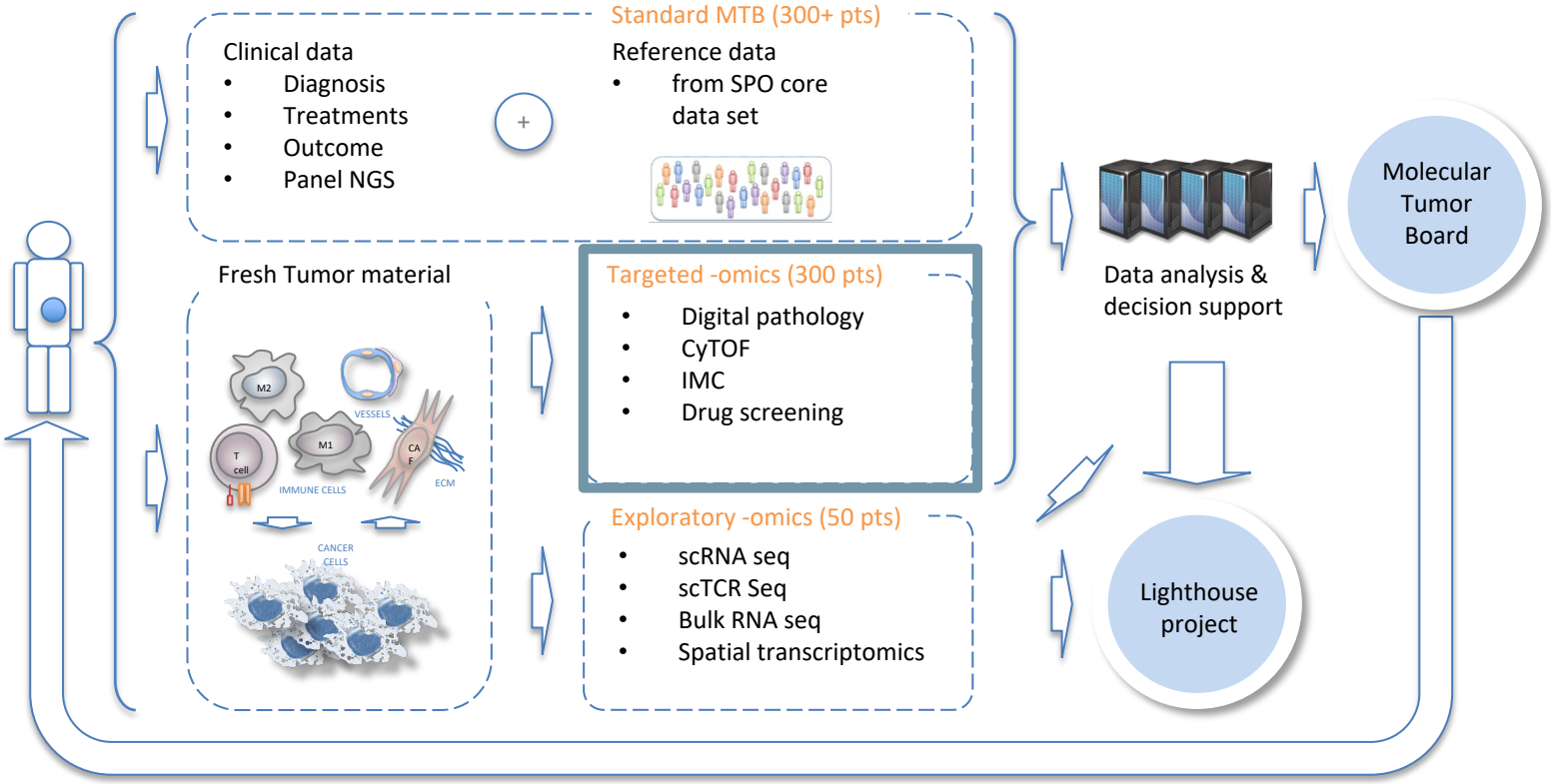
Milestone 2.1. Setup of Research Data Management System (RDMS) – in progress
Milestone 2.3-2.6 Onboarding of data generating facilities/labs – in preparation


Natalia Chicherova

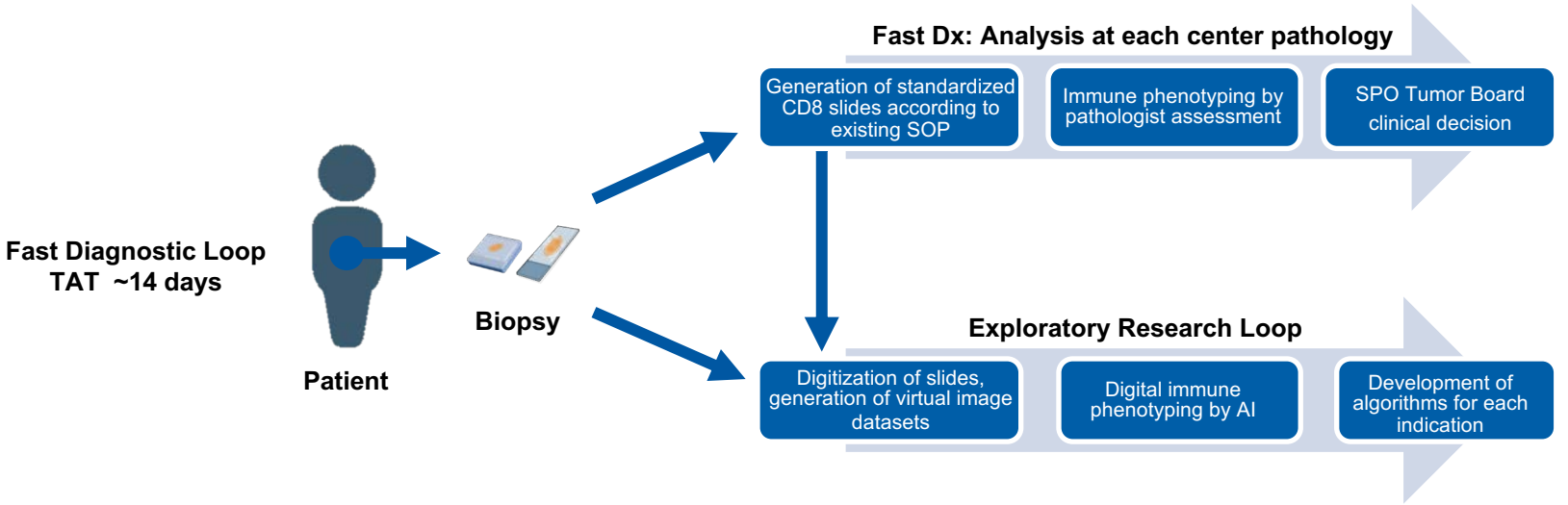

Shuqing Yu


Vipin Sreedharan

WP2.2 Definition and Implementation of SPO-NDS SOPs for experiments and analyses in Omics labs



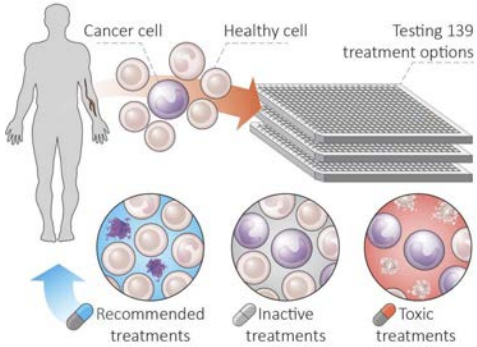
WP2.2 Definition and Implementation of SPO-NDS SOPs for experiments and analyses in Omics labs: Digital Pathology



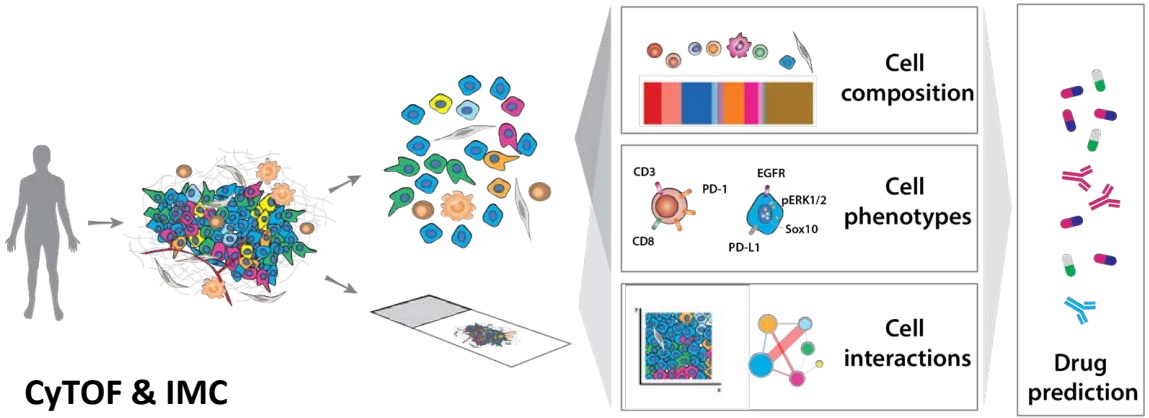
- **Centralized development**
- **Leverage learnings from the Tumor Profiler study and the Morphomolecular Pathology Lab project**
- **Roll out existing solutions (melanoma) to other indications**

Prof. Viktor Kölzer, University of Zurich,

Definition and Implementation of SPO-NDS SOPs for experiments and analyses in Omics labs: Drug screening, CyTOF, IMC



Drug screening



CyTOF & IMC

Drugs and antibody panels were aligned

Definition and Implementation of SPO-NDS SOPs for experiments and analyses in Omics labs: Sites

Patients recruited at all sites and SOC (NGS)				
CHUV	HUG	Insel	USB	USZ

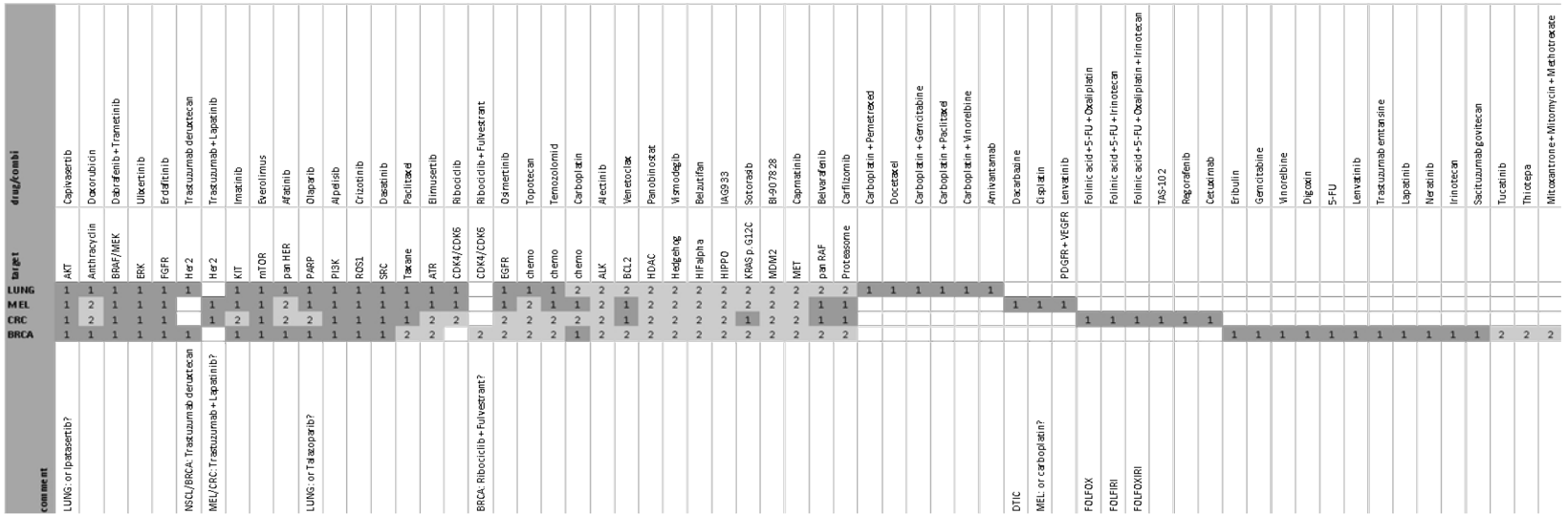
Digital pathology all entities at recruitment site				
CHUV	HUG	Insel	USB	USZ

	Technology		
	Single-cell suspensions		FFPE slides
Cancer type	Drug screening	CyTOF	IMC
Breast	UniBas, Mohamed Bentires-Alj		
Colorectal	ETHZ, Berend Snijder	ETHZ, Bernd Bodenmiller	
Lung	EPFL, Gaspard Pardon	UniBern, Deborah Stroka	
Melanoma	ETHZ, Berend Snijder	ETHZ, Bernd Bodenmiller	

WP2.2

Definition and Implementation of SPO-NDS SOPs for experiments and analyses in Omics labs: Drug panel

- Single cell suspensions
- Two tier testing system
- Tier 1: key inhibitors harmonized across tumor entities and relevant tumor specific drugs -> treatment recommendations at NTB
- Tier 2: only when enough tissue is available, confirmatory and exploratory



comment	drug/combi	target	LUNG	MEL	CRC	BRCA
LUNG: or Ipatasertib?	Capivasertib	AKT	1	1	1	1
	Doxorubicin	Anthracyclin	1	2	2	1
	Dabrafenib+Trametinib	BRAF/MEK	1	1	1	1
	Ulixertinib	ERK	1	1	1	1
	Erdafitinib	FGFR	1	1	1	1
NSCL/BRCA: Trastuzumab deruxtecan	Trastuzumab deruxtecan	Her2	1			
MEL/CRC: Trastuzumab+Lapatinib?	Trastuzumab+Lapatinib	Her2		1	1	
	Imatinib	KIT	1	1	2	1
	Everolimus	mTOR	1	1	1	1
	Afatinib	pan HER	1	2	2	1
LUNG: or Talazoparib?	Olaparib	PARP	1	1	2	1
	Alpelisib	PI3K	1	1	1	1
	Crizotinib	ROS1	1	1	1	1
	Dasatinib	SRC	1	1	1	2
	Paclitaxel	Taxane	1	1	2	2
	Elimusertib	ATR	1	1	2	
	Ribociclib	CDK4/CDK6	1	1	2	
BRCA: Ribociclib+Fulvestrant?	Ribociclib+Fulvestrant	CDK4/CDK6				2
	Osimertinib	EGFR	1	1	2	2
	Topotecan	chemo	1	2	2	2
	Temozolomid	chemo	1	1	2	2
	Carboplatin	chemo	2	1	2	1
	Alectinib	ALK	2	2	2	2
	Venetoclax	BCL2	2	1	1	2
	Panobinostat	HDAC	2	2	2	2
	Vismodegib	Hedgehog	2	2	2	2
	Belzutifan	HIFalpha	2	2	2	2
	IAG933	HIPPO	2	2	2	2
	Sotorasib	KRAS p.G12C	2	2	1	2
	BI-907828	MDM2	2	2	2	2
	Capmatinib	MET	2	2	2	2
	Belvarafenib	pan RAF	2	1	1	2
	Carfilzomib	Proteasome	2	1	1	2
	Carboplatin+Pemetrexed		1	1		
	Docetaxel		1			
	Carboplatin+Gemcitabine		1			
	Carboplatin+Paclitaxel		1			
	Carboplatin+Vinorelbine		1			
	Amivantamab		1			
	Dacarbazine			1		
	Cisplatin			1		
	Lenvatinib	PDGFR+VEGFR		1		
	Folinic acid+5-FU+Oxaliplatin				1	
	Folinic acid+5-FU+Irinotecan				1	
	Folinic acid+5-FU+Oxaliplatin+Irinotecan				1	
	TAS-102				1	
	Regorafenib				1	
	Cetuximab				1	
	Eribulin					1
	Gemcitabine					1
	Vinorelbine					1
	Digoxin					1
	5-FU					1
	Lenvatinib					1
	Trastuzumab emtansine					1
	Lapatinib					1
	Neratinib					1
	Irinotecan					1
	Sacituzumab govitecan					1
	Tucatinib					2
	Thiotepa					2
	Mitoxantrone+Mitomycin+Methotrexate					2

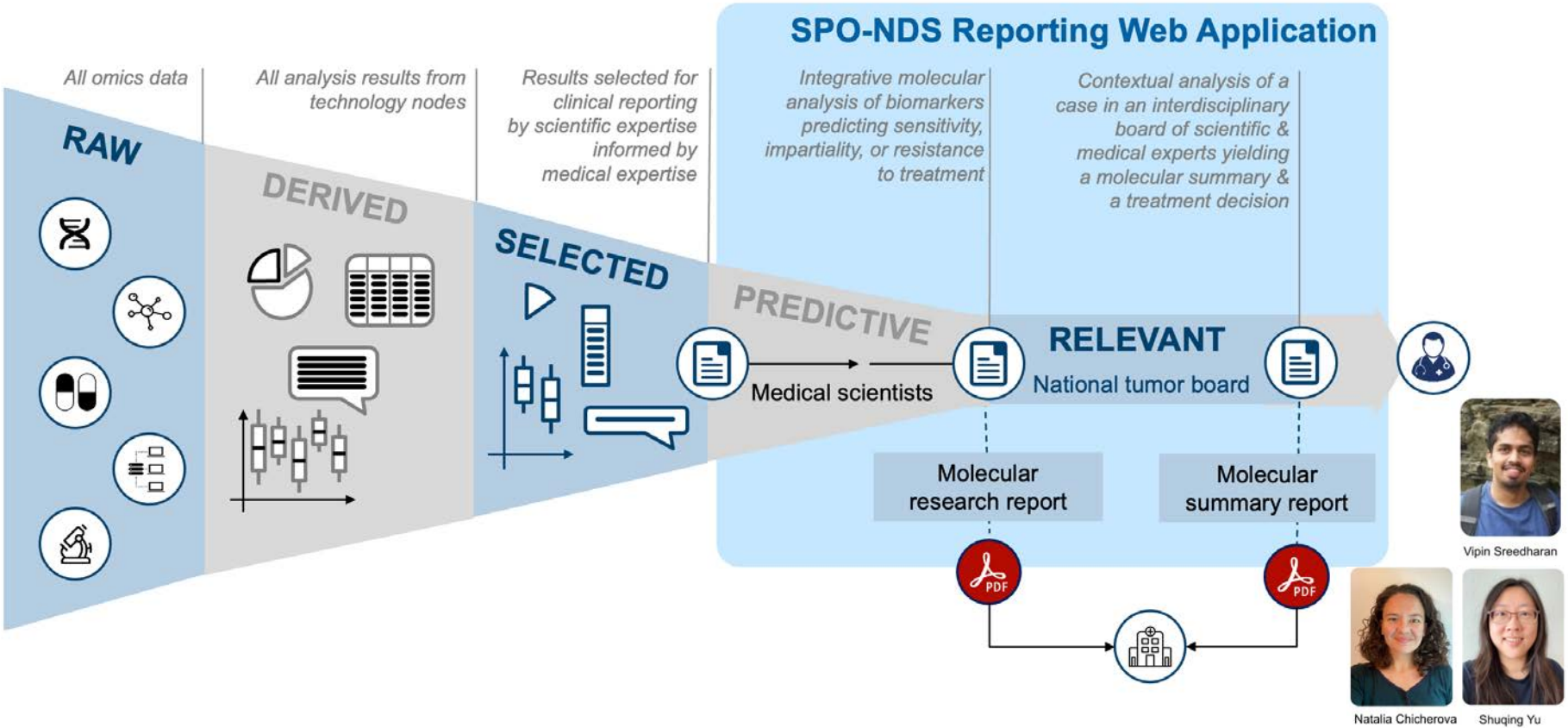
Definition and Implementation of SPO-NDS SOPs for experiments and analyses in Omics labs: CyTOF / IMC

- CyTOF single cell suspensions // IMC on FFPE slides
- Panels developed by Clinicians, CyTOF and IMC experts
- Backbone common to the 4 cancer entities (structural, immune, signalling and regulatory markers)
- Entity specific markers

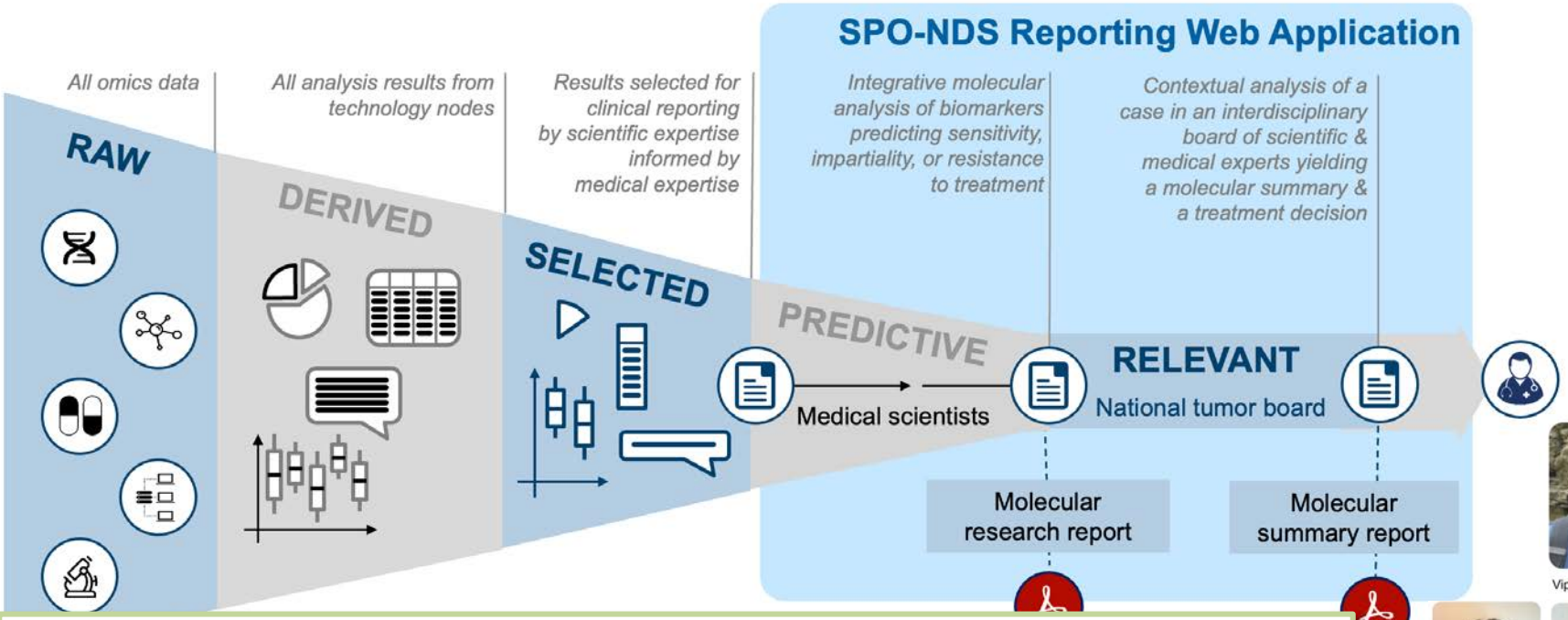
	CyTOF Backbone targetss	CD45	NGFR	KRT14	PCNA	Axl	HLAABC	cCASP	cPARP	CD31	PGR AB	pEGFR	pH2AX	CD274	CDK6	p53	CDK4	pAKT	pmTOR	AR	CAIX	Bcl2	PTEN		S100A4	FGFR1	VEGF	panCK	ERa		bCatenin	pRb	cMet	KI67	EGFR1		pERK1:2	ps6	CD117	CK8/18		cMyc	cPt	CD47
Indication specific	Lung																							CK5						Her3							Her2				PGP			
	Melanoma																							TYRP1						MelanA							Mitf				S100B			
	CRC																							porcupine						Her3							Her2							
	BRCA																							TROP2						Her3							Her2				CD011b			

	IMC Backbone targets	MPO		SMA	CD324	CD038	panCK	Vimentin		CD016	HLAABC	ICOS	Her2		CD274	CD045	CD223	CD366	FOXp3	CD004		CD068		CD020	CD008		Bcl-2	CD279	CA9	GrnzB	KI67	EGFR1	CD003		CD31	pmTOR	HLADR	ps6	pH2AX	CD56
Indication specific	Lung		cPARP						CD040					ERCC1							TCF1		CD134				CD117							TTF1							
	Melanoma		c-Myc						S100A1					gp100		NGFR					TCF1		TYRP1				CD117							SOX10/SOX9							
	CRC								CK8/18					CollV		GATA3					TCF1		Lamin A/C				PR							NaKATPase							
	BRCA								CK8/18					ERa		GATA3					KRT14		AR				PR							Cyclin-E							

Adaptation of TuPro processes for a national molecular tumor board and molecular tumor boards in university hospitals



Adaptation of TuPro processes for a national molecular tumor board and molecular tumor boards in university hospitals




Vipin Sreedharan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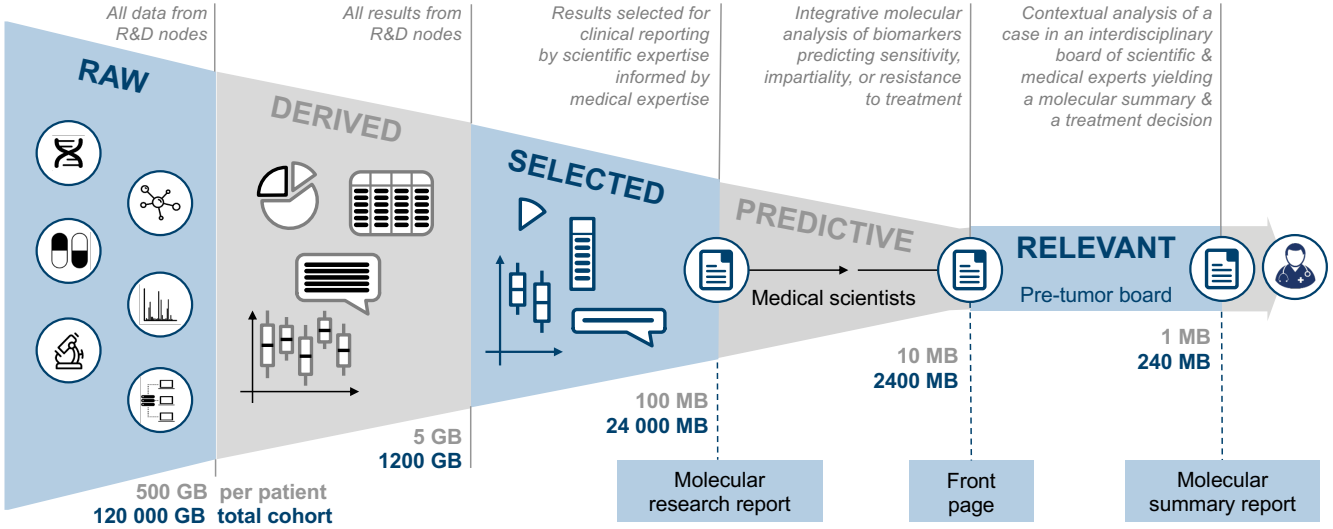
Milestone 3.1. Setup of the national tumor board web-application – in progress

Milestone 3.2. Design and implementation of reports for hospital-internal use – in progress

WP3

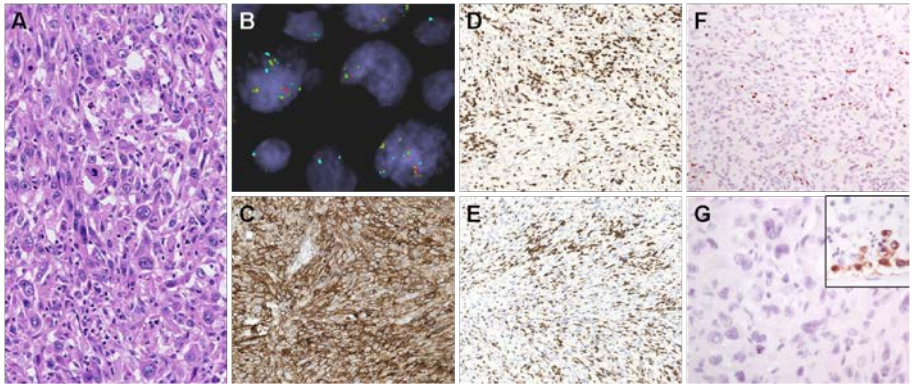
Adaptation of TuPro processes for a national molecular tumor board and molecular tumor boards in university hospitals

- All patients participating in the SPO-NDS program will be discussed at the local molecular tumor board
- The results of the targeted omics analysis will be discussed further within the framework of the regular national tumor board
- Minimal data set necessary for successful completion of each board meeting defined
- Tumor board co-leads: Simon Häfliger Bern, Petros Tsantoulis Geneva
- Site leads: Benjamin Kasenda Basel, Krisztian Homicsko Lausanne, Laura Boos Zurich



Molecular Tumor Board: example of clinical outcome

- Personalization focuses strongly on immuno-oncology
- Example of molecular tumor board case:
  - MPNST with PD-L1 amplification presenting a near CR on PD-1 blockade[1]
  - Patient followed in the private sector (Dr. Bohanes)



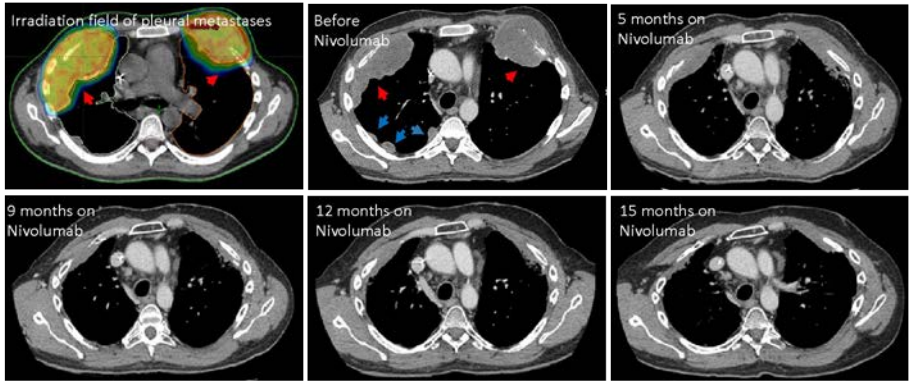
Deep response to anti-PD-1 therapy of metastatic neurofibromatosis type 1-associated malignant peripheral nerve sheath tumor with *CD274/PD-L1* amplification

Berna C. Özdemir [1,2], Pierre Bohanes[3], Bettina Bisig[4], Edoardo Missiaglia[4], Petros Tsantoulis[5], George Coukos[1,6,7], Michael Montemurro[1], Krisztian Homicsko[1,6,7], Olivier Michielin[1,6,7]

PD-L1

COPY NUMBER VARIATIONS (CNV)

REGION	GENES	TYPE OF VARIATION	ESTIMATED COPY NUMBER PER CELL
9p24-p23	*JAK2, CD274, PTPRD*	Amplification	≥5
9p22-p21	*CDKN2A, CDKN2B, FANCG*	Deletion	1
9q	All genes in the region	Amplification	≥5
11q	All genes in the region	Amplification	≥5



[1]Ozdemir, *JCO PO* 2019

WP3 Patients and Public involvement

Patient advisory board:

Tourane Corbière PhD (lead, SAKK patient advisory board)
Bernd Hägele PhD (deputy, SAKK patient advisory board)
Jane Shaw (Oncoplastic Breast Consortium)
Ursula Ganz-Blättler PhD (SAKK patient advisory board)

- Reviewed the patient consent forms
- Re-wrote the lay summary to be uploaded at the SPHN website.

Diverse set of skills across the team:

-Writing and proofreading in official Swiss languages and English
-Communication and dissemination
-Understanding of complex written materials
-Understanding of scientific questions, methods and statistical analysis
-Ability to analyze and synthesize
-Project management
-Public & Patient Involvement in research
-Collaborative leadership

PPI activities plan

Study Phase	Activity	Purpose
Study design & funding application	Attend all full team meetings and reviews	a). To ensure the team is clear on the impact of its decisions on patients. b) educate the wider project team on PPI and how to incorporate it more comprehensively in the mutual work
Study design & funding application	Develop PPI strategy and associated budget	To ensure that there is a clear strategy and sufficient funding for a good level of PPI activities in the project
Management & study process	Quarterly scientific board meeting	To make sure that PPI is well represented at the executive level of the project, and patient impact considered and understood for all key program decisions
Management & study process	Review and sign off on all patient facing documents. (e.g., consent forms)	To ensure that all information leaflets, forms etc are understandable for patients and contains all relevant points that would concern/be of interest to patients.
Management & study process	Review and sign off of wider patient facing communication materials. (e.g., patient & public information page(s) on the program website, information leaflets etc).	To ensure that all public communication channels relating to the project are understandable to the lay community, including all relevant points that would concern/be of interest to patients.
Dissemination & implementation	Activate the wider public audience for SPO- NDS	Leveraging particularly the SAKK PPI advisory board wider network to ensure that the project is well understood by the appropriate Patient & Public Interest groups in Switzerland to support accrual and therefore bring greater benefit to patients.
Evaluation	In partnership with the executive board, develop evaluation strategies for PPI activities	Ensure that the PPI involvement in the project is as effective as possible and continuously reviewed and improved.

Further defining how to ensure that the patient perspective is represented practically in the project using the PPI activity plan as a landmark.

WP4

Comparative tumor atlas of patients with different levels of immuno-responsiveness (Lighthouse research project)

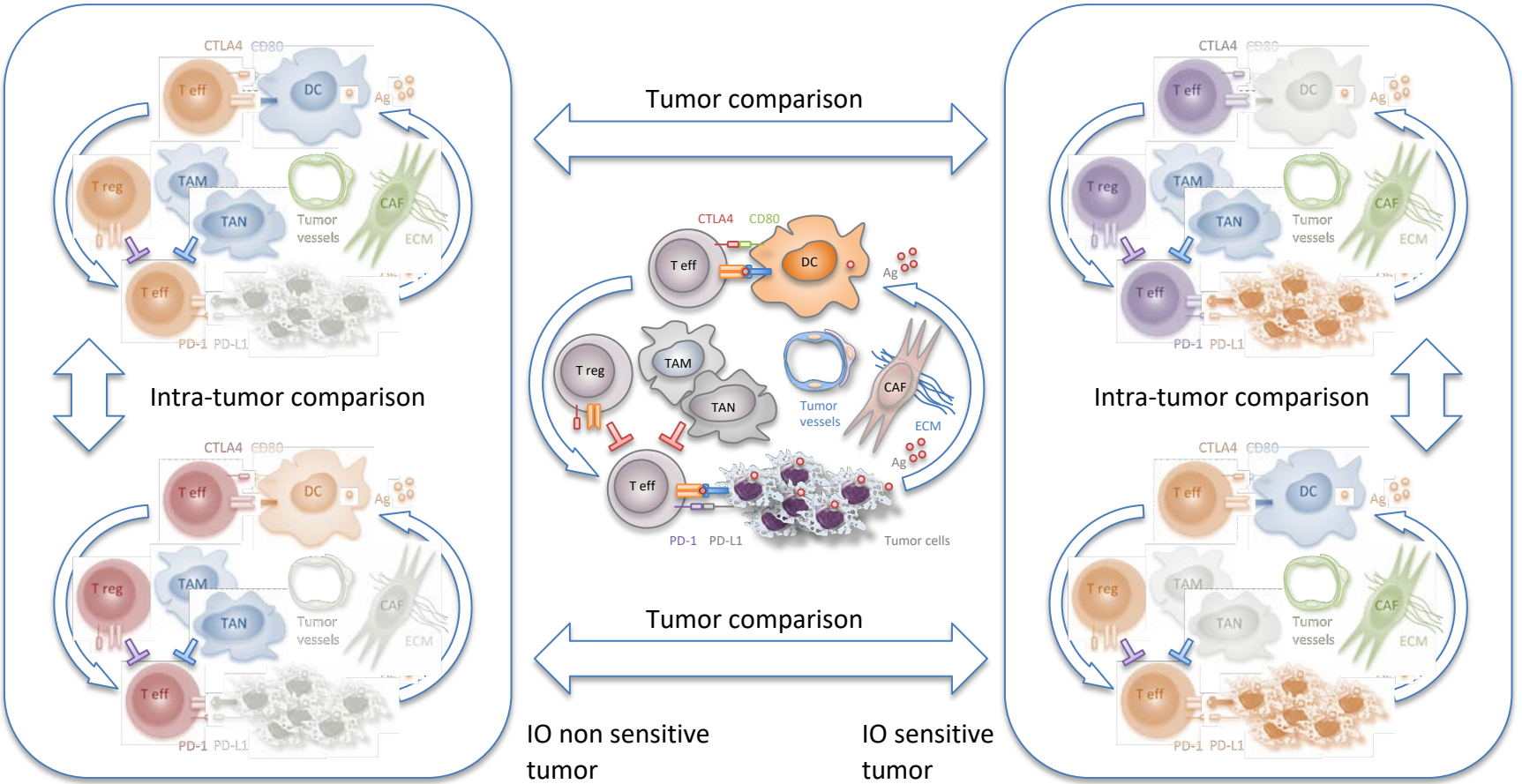
Research question: What are the mechanisms of primary and acquired immunotherapy resistance within and between tumors with different immuno-reactivities?

Comparative immune-oncology approach at the single-cell and multi-omics levels to identify **shared features of primary and acquired resistance to IO**. In particular, we will compare the cancer-immune ecosystems of patients and tumors that respond well to IO to those who fail to mount antitumor immune responses to IO.

Sub cohort selection will start as soon as patient recruitment begins.

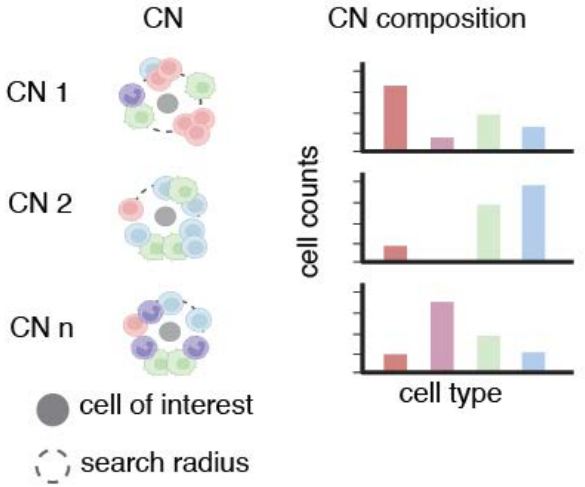
WP4

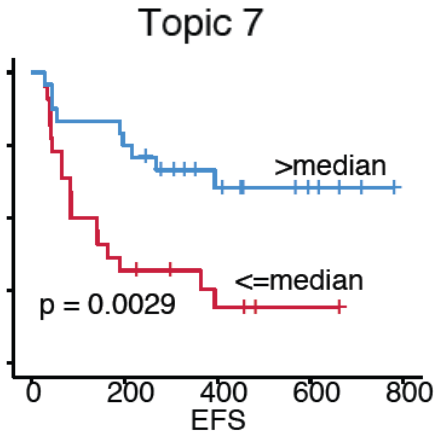
Comparative tumor atlas of patients with different levels of immuno-responsiveness (Lighthouse research project)

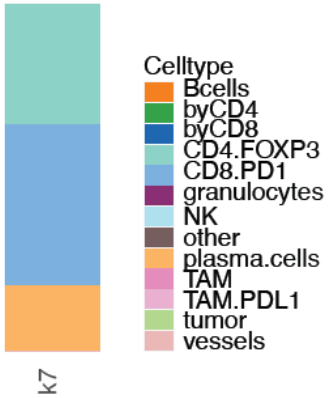


WP4.1

Comparative tumor atlas of patients with different levels of immuno-responsiveness: TuPro re-analysis







Outlook

- BioMedIT data delivery tests to validate pipelines [Q4 2023 – Q1 2024]
- Patient data for retrospective cohort [Q2-Q3 2024, depends on start of patient enrollment]
- Finalization of data delivery process definitions & LabKey setup for main targeted omics [Q4 2023 – Q1 2024]
- Finalization of national tumor board web-application [Q4 2023 – Q1 2024]
- Onboarding of main targeted omics stream labs [Q4 2023 – Q1 2024]
- Refinement of sample flow and processing SOPs [Q4 2023 – Q1 2024]
- Interlaboratory test to evaluate the feasibility of each site to perform targeted omics analyses [Q4 2023]
- Results from this interlaboratory test used for a mock run of the national molecular tumor board [Q4 2023]
- Patient enrolment [Q1 2024]

SPO-NDS consortium

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Bernd Bodenmiller, UZH ETHZ
Andreas Wicki, USZ
Benjamin Kasenda, USB
Berend Snijder , ETHZ
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Sylvain Pradervan, CHUV
Amanda Ochoa Espinosa, UNIBAS

AND close to 80 more collaborators across CHUV, EPFL, ETHZ, NEXUS, HES-SO, HUG, INSEL, KISPI, SAKK, UNIBAS, UNIBE, UNIGE, UNIL, USB, USZ and UZH.

SPO-NDS consortium

Kick off retreat Nov 2022

Swiss Personalized Oncology

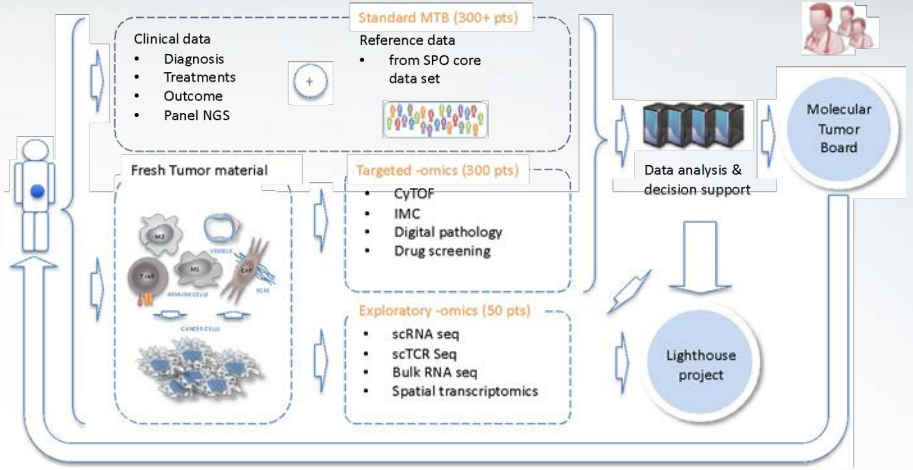
2nd monitoring meeting | 19.09.2023

THANK YOU FOR YOUR ATTENTION!

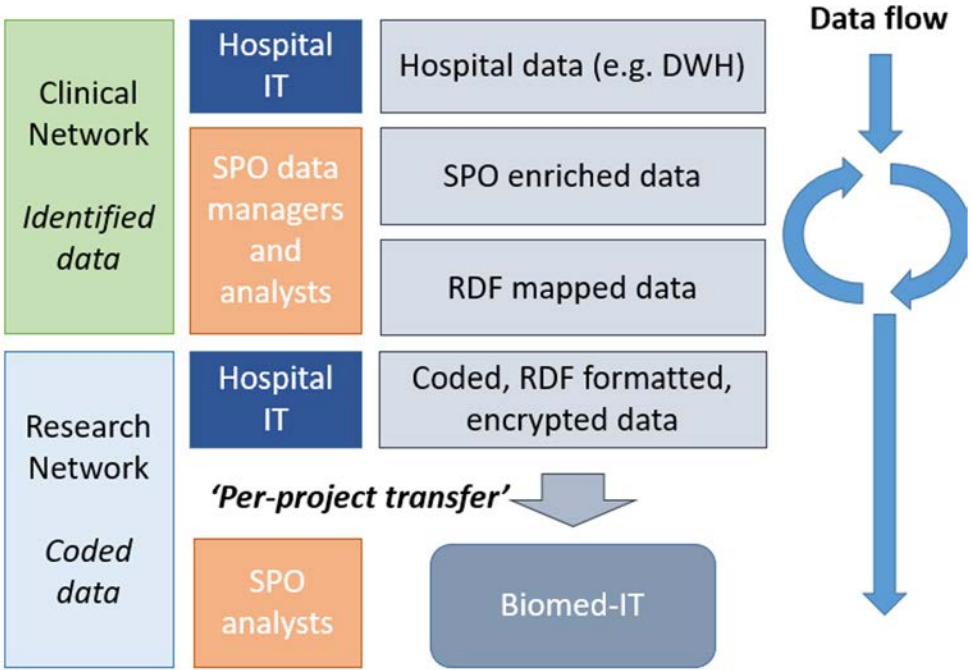
SPHN Swiss Personalized Health Network

Strategic Focus Area
Personalized Health and Related Technologies

Backup slides



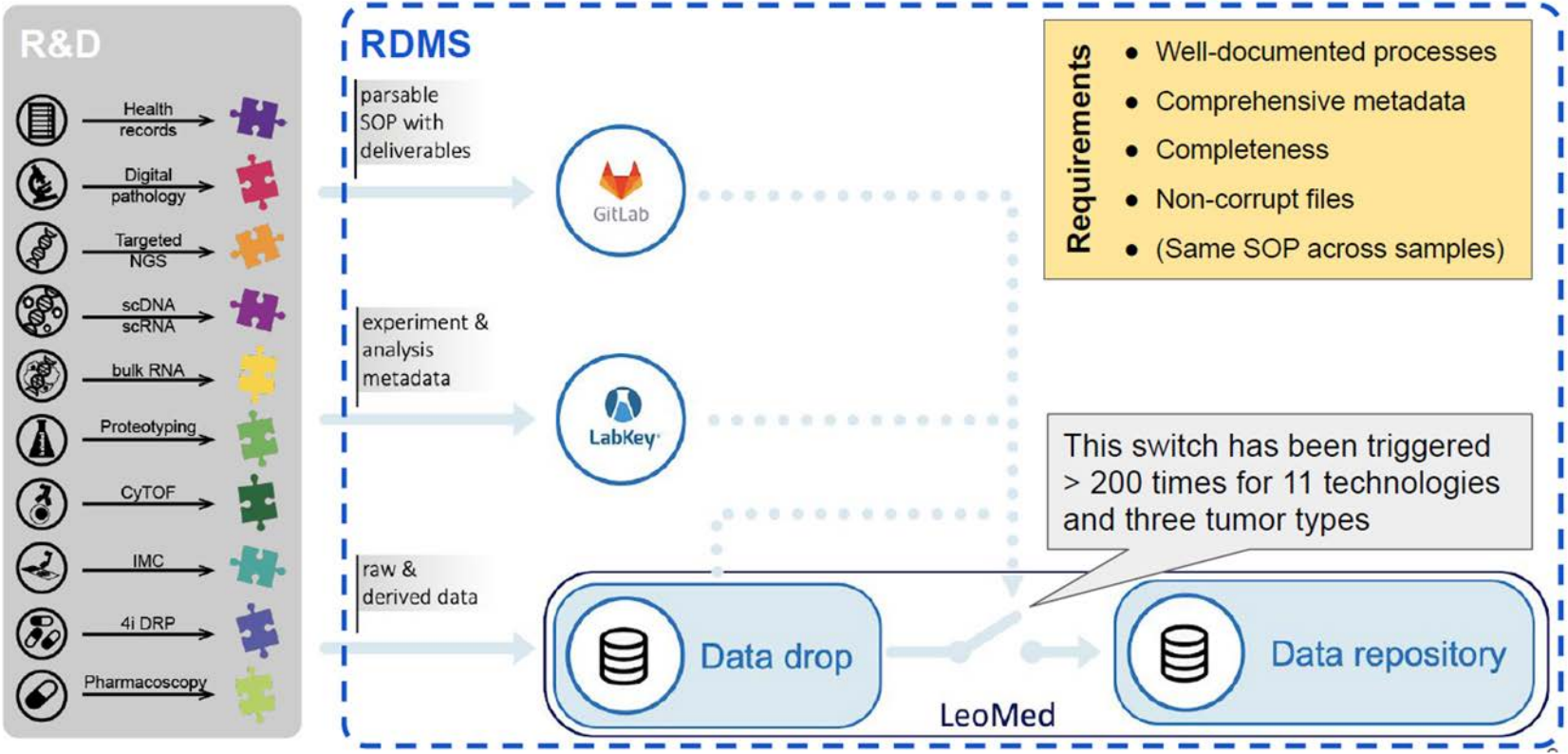
Clinical Data flow



For re-usability SPO data is recoded from within the hospital.

Same approach as the one used for the SPO driver

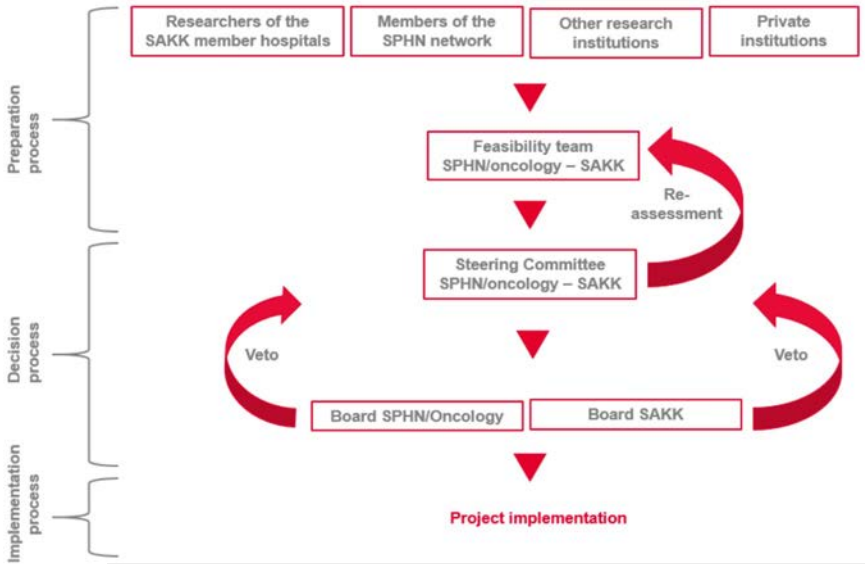
Tumor Profiler RDMS



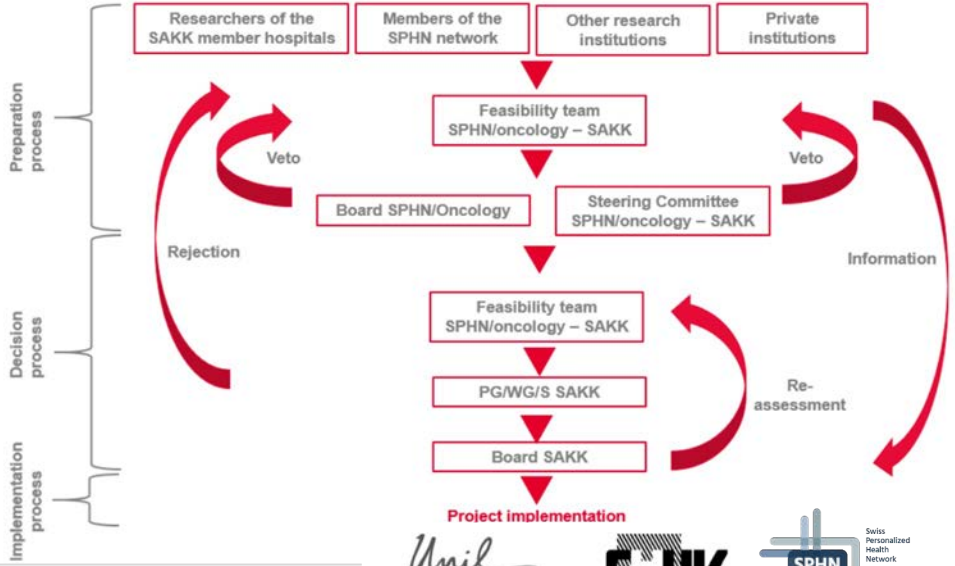
Data Governance (SPO-NDS & SCORED)

- For data access requests that involve both SPO-NDS datasets and the SCORED database developed by SAKK, specific approval processes and workflows have been defined (see Collaboration Guidelines SPO SAKK)

1) Submission process for research projects of retrospective data analysis



2) Submission process for registry projects (new variables or new patients)



SPO-NDS: infrastructure

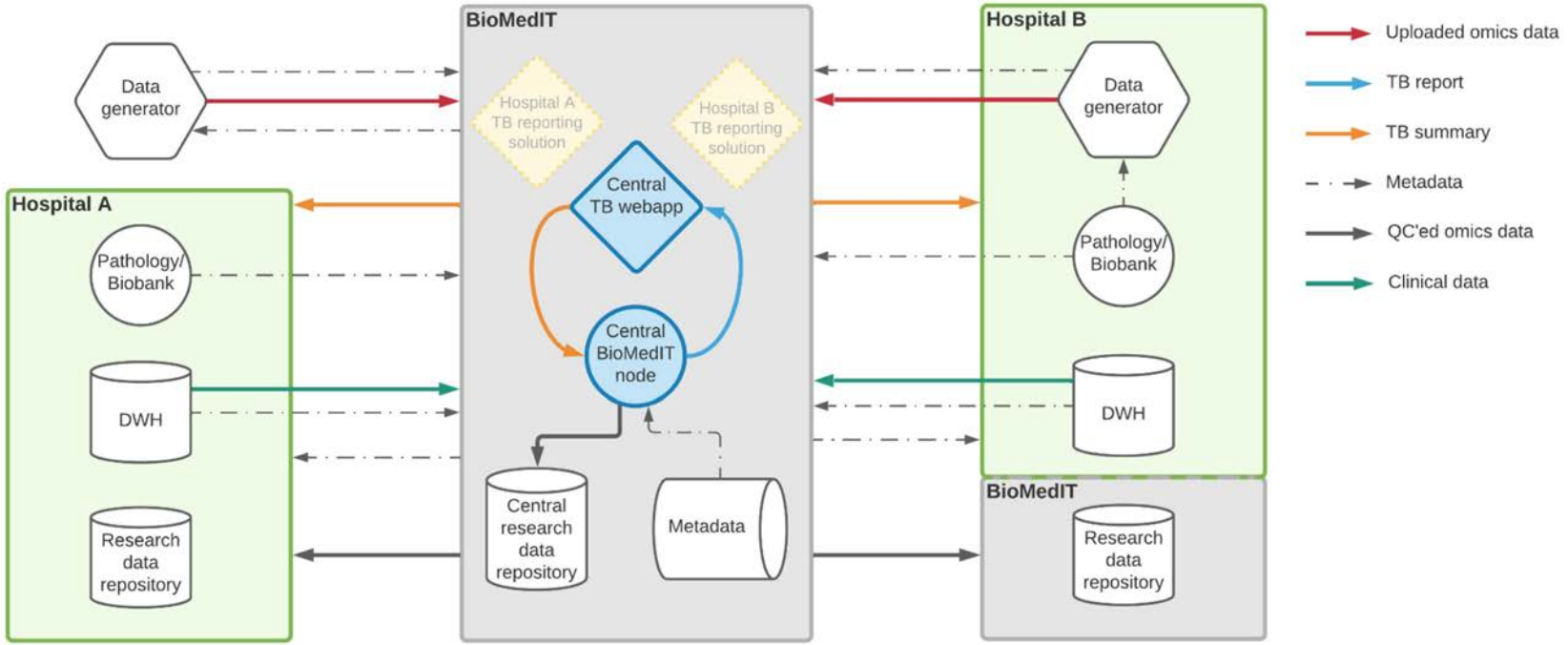
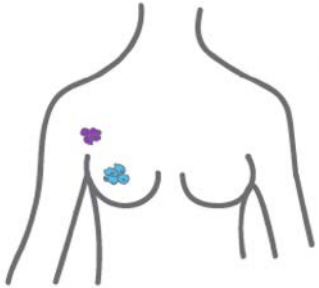
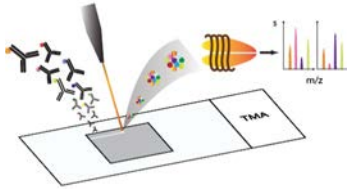


Figure 2. Overview of 'omics' data stream from data generation to data repository.

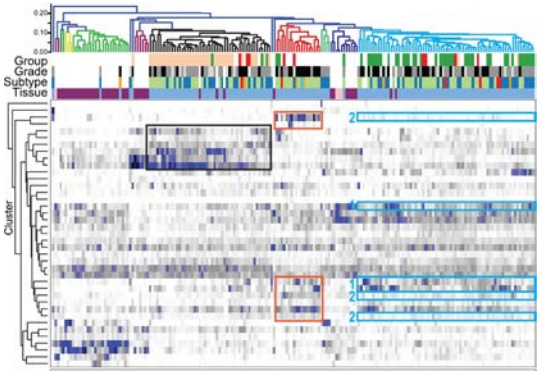
Example of IO predictive biomarker for breast cancer

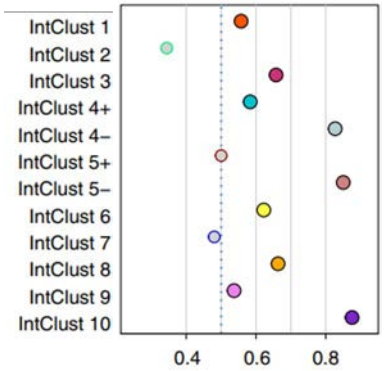


Primary breast cancer



144 patients
CyTOF
693 IMC





Patient group identification
for immune checkpoint therapy

Wagner, Cell 2017. Danenberg, Nature Genetics 2022.

SPO-NDS Project Review Dashboard

Project Leaders:
Olivier Michielin and Bernd Bodenmiller

Date: 19th September 2023

Overall Project: Status  **Outlook:** 

Swiss Personalized Oncology

Project Scope and work packages

- **WP1 Consolidation and expansion of SPO core dataset** in all 5 University Hospitals and selected participating non-university hospitals
- **WP2 Standardization**, management, and organization of multi-dimensional data
- **WP3 Adaptation of TuPro processes** for a national molecular tumor board and molecular tumor boards in university hospitals
- **WP4 – Lighthouse Comparative** tumor atlas of patients with different levels of immuno-responsiveness (Lighthouse research project)

Melanoma: Patients who have failed PD-1 adjuvant therapy and who are candidates for first line systemic treatments.

Non-small cell lung cancer: Metastatic squamous NSCLC or non-oncogene-driven non-squamous NSCLC patients from the second line.

Colorectal cancer: Microsatellite-instable CRC and microsatellite-stable CRC from the second line.

Breast cancer: Advanced triple negative breast cancer and estrogen receptor positive.

Key activities & milestones achievements*

- **CA**: Finalized July 2023.
- **Clinical Ethics protocol** Approved on August 2023.
- SPO specific data concepts (not yet in the SPHN dataset) submitted to the DCC.
- Targeted omics groups harmonized their SOPs and developed SPO project geared analyses panels.
- Patient sample flows defined.

Program Status and Milestones adjustments

	Status	Outlook
WP1		
WP2		
WP3		
WP 4		

Comments

- Patient recruitment delayed due to CA
- Solutions to identify data not yet in CDW being evaluated
- M2.1 delayed by technical issues. M2.3-2.6 In the process of defining improved data delivery processes. M2.2 Refinement of targeted omics SOPs
- 3.5 PPI team defining how their diverse skills can be used to ensure patient perspective in the project.
- WP4 Exploratory omics technologies under evaluation.

Focus Areas for next 6 months

- Interlaboratory test to evaluate the feasibility of each site to perform the analyses proposed
- Mock tumor board.
- Start patient recruitment with presentation at the national tumor board

*For detailed and technical achievements see report