

SAKK 86/18 ONCONAVIGATOR

Prospective population-based real-world data registry for patients with advanced solid tumors.

Data collection (step I), development (step II), validation (step III), refinement and implementation (step IV) of predictive treatment algorithms by artificial intelligence

Rational: Challenges in personalized cancer care



Perplexed doctor reading a NGS report.

Deducing causality between gene mutation and possible drug-response in a clinical off-label scenario is very challenging!



An even more perplexed doctor trying to organize off-label drugs

Some Expected Treatment Outcomes

Some Serendipitous Experiences

Many Failures



„N = 1“ approach

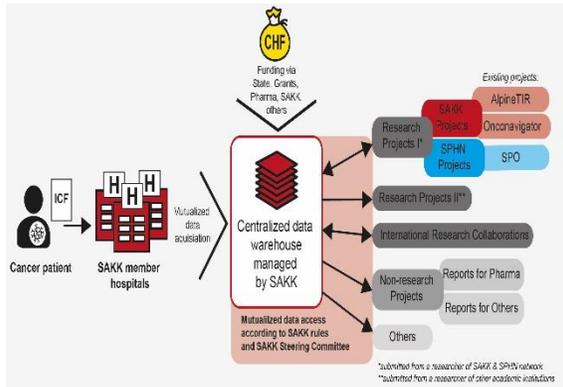
Problems/Challenge:

- $N=1$ trials are not informative
- Collective learning = 0
- Massive waste of money & health resources

Main Objectives

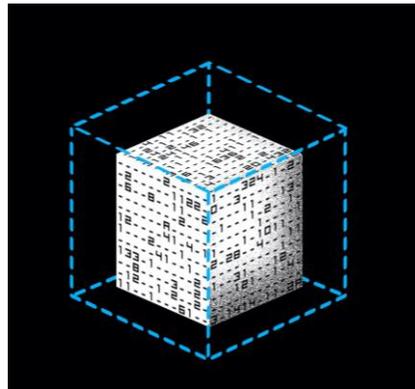
- **To build a prospective national real-world data registry, linked with SAKK RWD (real world data registry) and with SPHN/SPO, for patients with advanced solid tumors after failure of standard therapies (step I).**
- **To endorse precision oncology in Switzerland by the systematic implementation of multigene NGS panel tests into routine diagnostics and by guidance by a virtual molecular tumorboard**
- **To enable access to cancer drugs for the ONCONAVIGATOR treatment line by a partnership between SAKK, pharmaceutical companies, Swiss health insurance companies and health authorities**
- **To develop (step II), validate (step III) and implement (step IV) predictive treatment algorithms for the full spectrum of solid tumors and for all types of cancer drugs listed on the “Spezialitätenliste” based on artificial intelligence (AI) technology**
- **To build a comprehensive database that serves as solid basis for future clinical and translational research projects (e.g. phase I studies with new agents for a molecularly defined subgroup)**

Trial Design



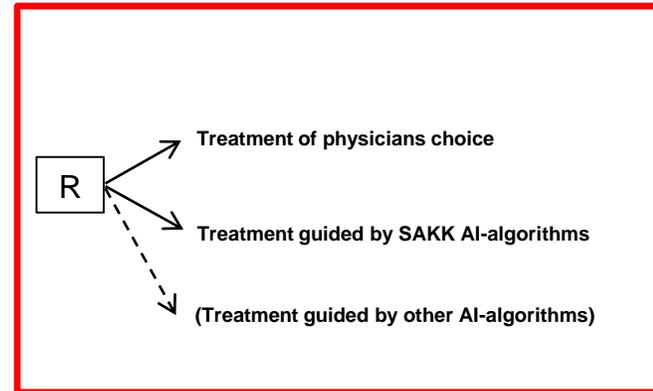
STEP I

Onconavigator is a key project of SAKK RWD



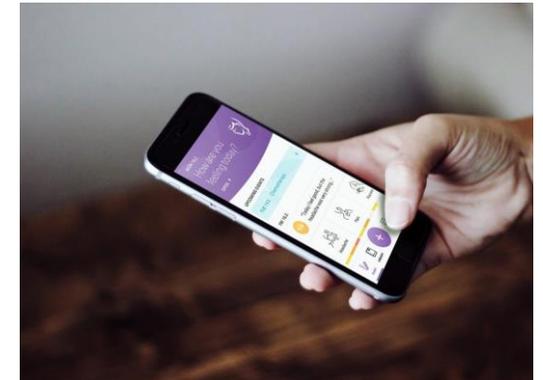
STEP II

Predictive algorithms by AI



STEP III

Randomized phase III trial for validation of algorithms-supported treatment decisions



STEP IV

Cont. refinement and implementation of predictive algorithms into clinical practice



Optionally cases are discussed at local tumor board

Swiss Virtual Molecular Tumor Board



Oncologist requests S-VMTB for support



Oncologist sends medical records to SAKK CC



SAKK asks an available molecular oncologist for taking the lead



Molecular oncologists and pathologist are commenting on recommendations



Molecular oncologist in lead writes a standardized report and submits the S-VMTP recommendations to SAKK CC within 5 working days

SAKK CC sends S-VMTB recommendations to oncologist and documents final treatment decision.
S-VMTB recommendations are available on chat platform

Project Plan

- 12/2019 Expected accrual estimation by SAKK sites
- 03/2020 Final assessment by SAKK board and final protocol
- 05/2020 First patient in SAKK RWD (step 1)
- Continuous relationship between SAKK, pharmaceutical companies, Swiss health insurance companies and BAG to enable access to cancer drugs for the ONCONAVIGATOR treatment line
- 2023 Development of predictive treatment algorithms by artificial intelligence (step 2)
- 05/2024 Start of phase III trial (step 3)
- 01/2026 Implementation of AI based algorithms into clinical routine (step 4)

Summary

- Onconavigator endorses personalized oncology treatment tailored to their individual cancer type, stage, molecular profile, and their overall health status.
- Onconavigator aims to support, that every cancer patient with as strong rationale for precision oncology should receive a drug trial with the best possible targeted drug(s)
- Algorithms are continuously being loaded with clinical, pathologic, genomic, as well as outcome data to provide up-to-date, high-quality, population-based and real-world information
- Algorithms will be evaluated in a phase III trial versus standard of care
- Main Objective of ONCONAVIGATOR: to finally develop a routine tool that supports Swiss oncologists in complex treatment decisions