

MUNI
MED

CZEch Clinical Research Infrastructure Network



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CZEch Clinical Research Infrastructure Network

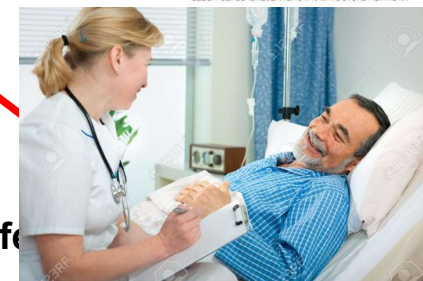
MISSION:

to create a sustainable research infrastructure network for multicenter academic clinical trials in the Czech Republic. Development of CZECRIN as the Czech national node within the ECRIN-ERIC will allow better linking of the Czech clinically-oriented researchers with application sphere at EU level.

VISION:

“when science help patients”

European Biomedical Research Infrastructures

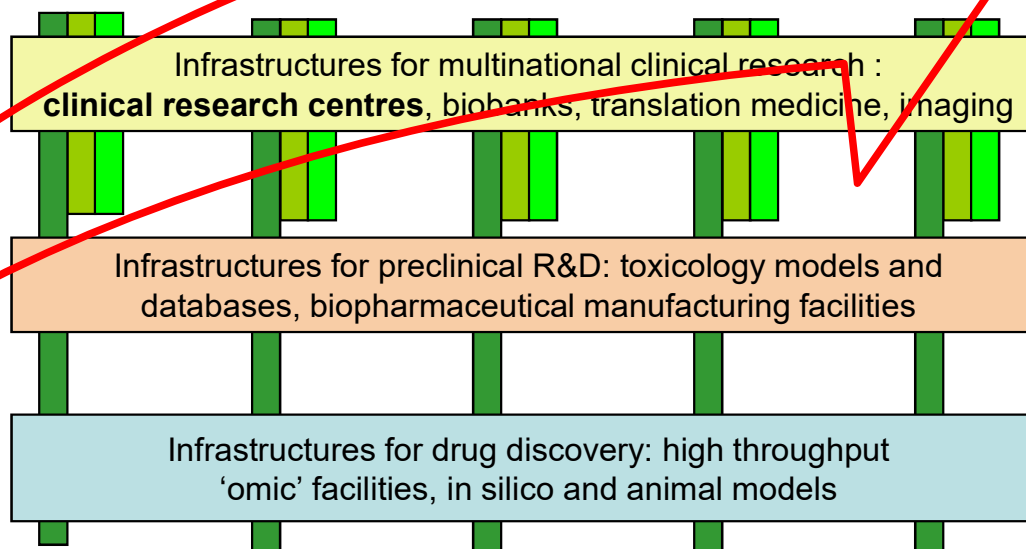


EU-wide infrastructures networks

**Clinical/Medical
(ECRIN, EATRIS, BBMRI)**

EU-wide disease-oriented networks

cancer brain diabetes inflammation info



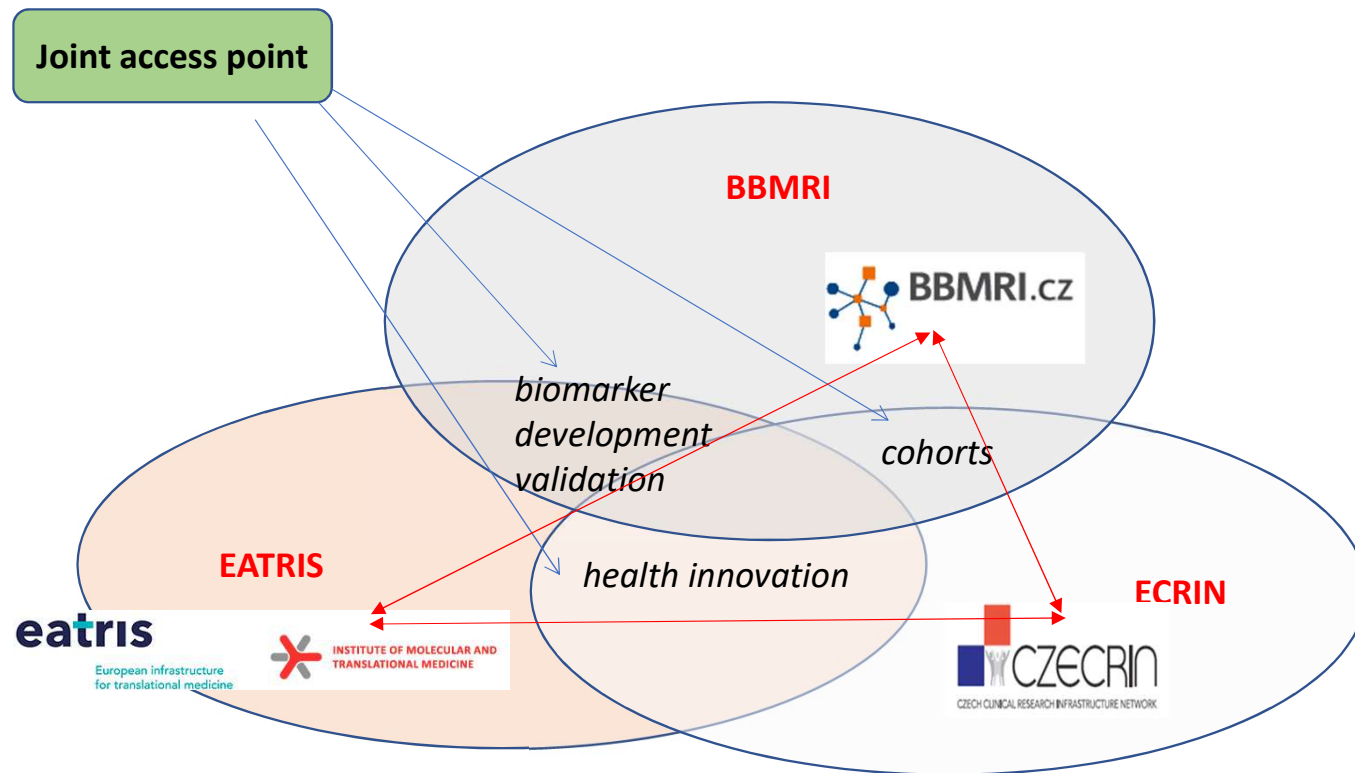
Preclinical

Basic research



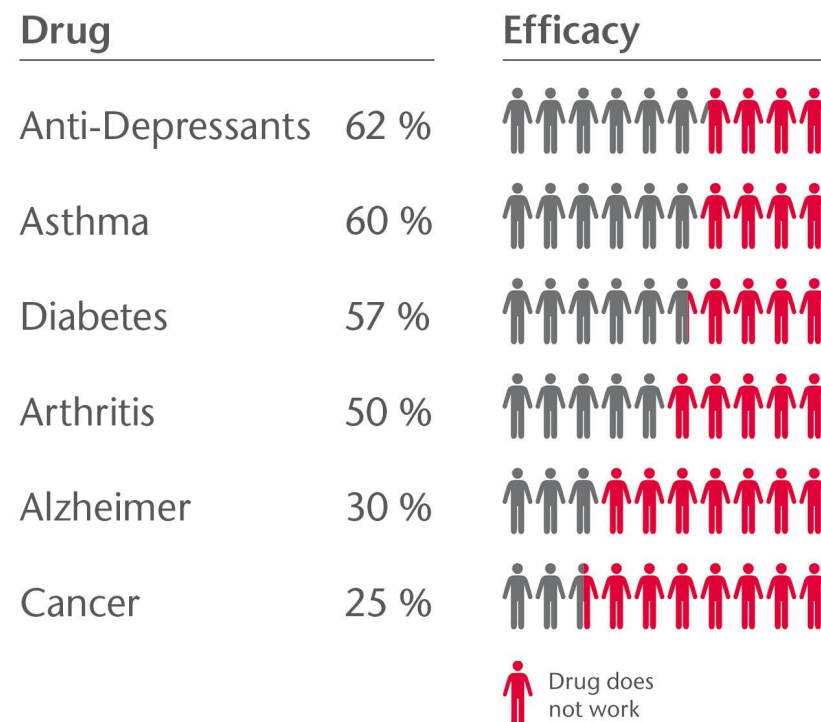
**Research networks
Investigators networks
Patients' registries**

Cooperation of medical research infrastructures



CZEch Clinical Research Infrastructure Network

- podporovat inovační činnosti v oblasti ochrany zdraví, se zvláštním důrazem na rozvoj **nekomerčních klinických studií** (mimo oblast fungujících komerčních studií iniciovaných průmyslem)
- jejich cestou **iniciovat a realizovat vlastní** vědecký výzkum a vývoj
- tímto přinášet vlastní výsledky, které jsou základem pro **řízení lékařské a zdravotní péče na základě důkazů vědeckých**
- **financování pro nekomerční studie na národní úrovni** (mimo systém komerčních sponzorů)



Key Objectives ECRIN-ERIC and CZECRIN 2019

Medical research is now facing **outcome-based personalised trials**

- Phase III / Cohort trials
- Real-World/Effectiveness
- Outcome-Based Research (Patient-oriented)

✓ Full Members

DE, ES, FR, IT, PT,
NO, IRL, HU, CZ
(January 1st, 2018)

✓ Observers

CH, SK



Medical research is now facing **a data challenge**

- data sharing and multimodal data management
- Re-using the electronic health records for research purposes (cohorts and trials) - avoiding duplication in data collection (EOSC),

CZEch Clinical Research Infrastructure Network

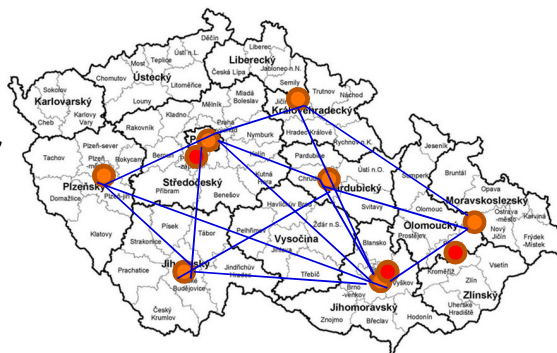
- In operation phase since March 2014
- Included in Roadmap for Large Research, Development and Innovation Infrastructures in the Czech Republic
- Under responsibility of with Ministry of Education, Youth and Sport
- Budgeted till 12/ 2019 (approved for 2020-2022)



CZEch Clinical Research Infrastructure Network

Univerzity Module

- Masaryk University, Brno – founding member
- Charles University, Prague
- Palacky University, Olomouc
- University of Veterinary and Pharmaceutical Sciences Brno



Clinical Module (members of clinical CTU network)

- University Hospital St. Anne's Brno – founding member
- University Hospital Brno - 2014
- University Hospital Motol - 2015
- University Hospital Ostrava - 2015
- Masaryk Memorial Cancer Institute - 2015
- University Hospital Hradec Králové - 2016
- General University Hospital in Prague – 2016
- University Hospital Pilsen – 2019
- University Hospital Královské Vinohrady– Signature of agreement in process
- Thomayer's Hospital in Prague – Agreement negotiation
- National Institute of Mental Health - in discussion

CZEch
CZECH CLINICAL RESEARCH INFRASTRUCTURE NETWORK

... WHEN SCIENCE HELPS PATIENTS

Comprehensive design of academic clinical research

Clinical module

- The University Hospital Brno
- St. Anne's University Hospital Brno
- Masaryk Memorial Cancer Institute
- University Hospital Ostrava
- University Hospital Hradec Králové
- University Hospital in Motol
- General University Hospital in Prague

University module

- Masaryk University
- Charles University in Prague
- University of Veterinary and Pharmaceutical Sciences Brno
- Palacky University Olomouc

Excellence in clinical trials:

- Early phases I/IIa
- Rare diseases
- Regulatory and ethical science
- Advanced therapy medicinal products
- Clinical trials management

www.czecrin.cz

CZEch Clinical Research Infrastructure Network - WPs

WP CZECRIN_{ATMP} - Clinical Trials with Advanced Therapy Medicinal Products

WP CZECRIN_{PED MED} - Pediatric Clinical Trials

WP CZECRIN_{RARE} - Clinical Trials in Rare Diseases – Regulatory Challenges

WP CZECRIN_{PER MED} - Personalised Clinical Trials – Stratified Precision Medicine

WP CZECRIN_{NEURO} – NEURO STROKE programme (new WP starting from 2020)

WP CZECRIN_{ATMP} - Clinical Trials with Advanced Therapy Medicinal Products

Autologní „dendritic-cell derived“
somatobuněčná terapeutická vakcína u
dětských onkologických pacientů

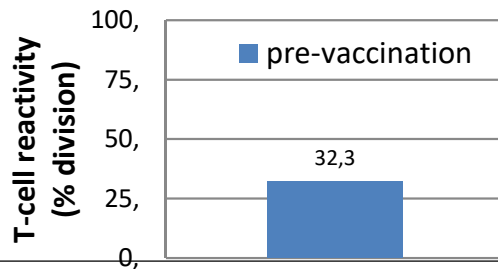
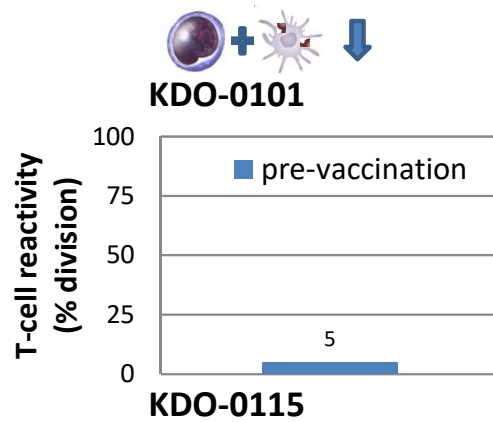
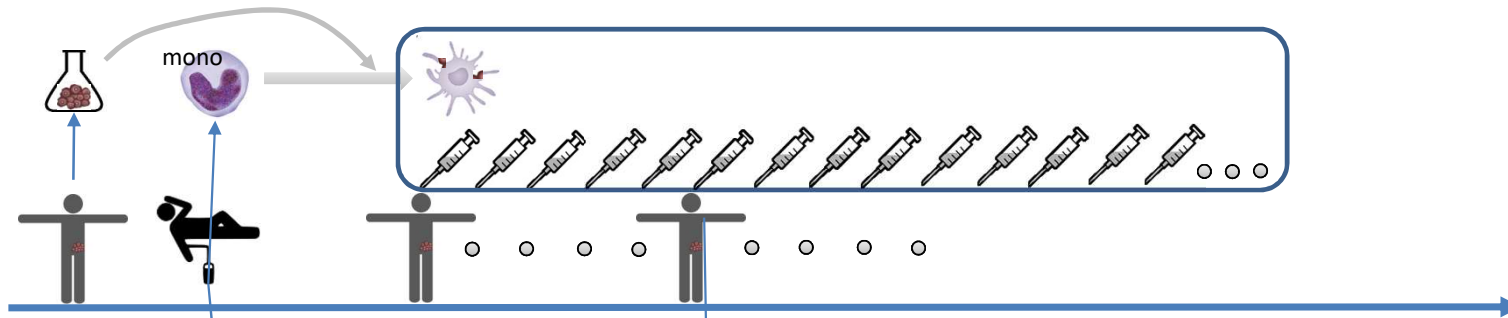
Farmakologický ústav LF MU, Advanced
Cell Immunotherapy Unit

Akademické klinické hodnocení fáze I
KDO_DC1311, EudraCT:2014-003388-39



„Proof of concept“: personalizovaná protinádorová vakcína na bázi dendritických buněk stimuluje pre-existující imunitní odpověď konkrétního pacienta proti jeho nádorovým antigenům

...and some newer data: Ex vivo evaluation of post-vaccination T-cell reactivity to DC-presented antigens



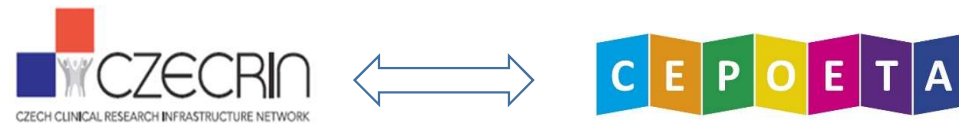
➤ **personalized anticancer DC-based vaccine stimulates pre-existing immune response against cancer antigens of individual patients**

WP CZECRIN_{PED MED} - Pediatric Clinical Trials

Partnership with pediatric investigation networks

Development of tools for pediatric population

Central European Pediatric Oncology Early Trial Alliance



Example of CZECRIN close collaboration



WP CZECRIN_{PER MED} - Personalised Clinical Trials – Stratified Precision Medicine/ Regulatory Challenges

Pokračující relevantní základní výzkum/ adresující relevantní klinickou potřebu !

Validace výzkumu a vývoje biomarkerů na všech jeho stupních
Inovativní design klinických studií !!

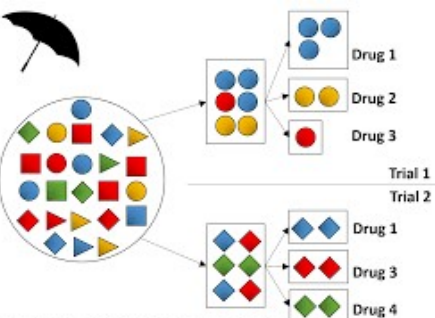


Figure 2: Umbrella trial based on histology and genotype

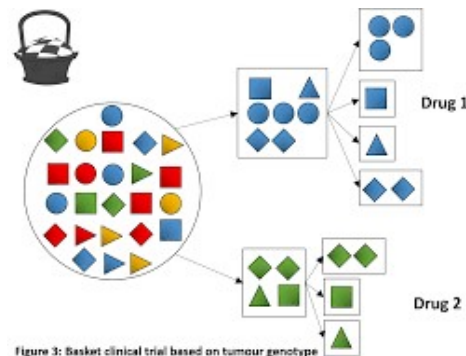


Figure 3: Basket clinical trial based on tumour genotype

Pragmatic Trials...**Real-World Effectiveness**

N- of-1 clinical trials...

Learn from every patients – not just clinical trial patients !

CZECRIN Clinical Trials



**RCC_DC
-2011**

**CZECH-
ICIT**

**MEMMAT
TIGER**

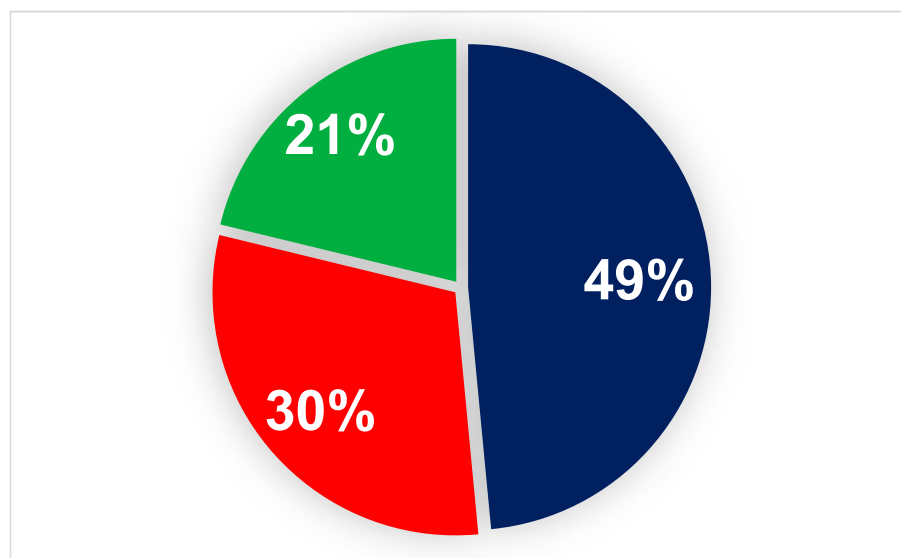
**Dauno
Double
PNET 5**

**POEM
Fluorocholin
KDO_DC1311**

**GabaNeuBol
Disulfiram
Ependymoma
STOPRHEA
ReNETA
EuroHYP
VISION-DMD
CPU001
RIMINI**

**DISCHARGE
SECURE
FAIRPARK II
CPU002
GASTRO-PET
CELLMIN**

**NISCI
PrOof
TENSION
PopART
SEOTP
DESFODEL
GlioART
CD133
MSC-MU
RASMIR**



CZECRIN – national IIT

ECRIN – FP7, H2020

CZECRIN – international IIT

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**Děkujeme za spolupráci
všem partnerům
a těšíme se na další...!**



A FNUSA
ICRC