

M U N I
M E D

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 infe

Infrastructures for multinational clinical research :
clinical research centres, biobanks, translation medicine, imaging

Infrastructures for preclinical R&D: toxicology models and
databases, biopharmaceutical manufacturing facilities

Infrastructures for drug discovery: high throughput
'omic' facilities, in silico and animal models

Preclinical

Basic research

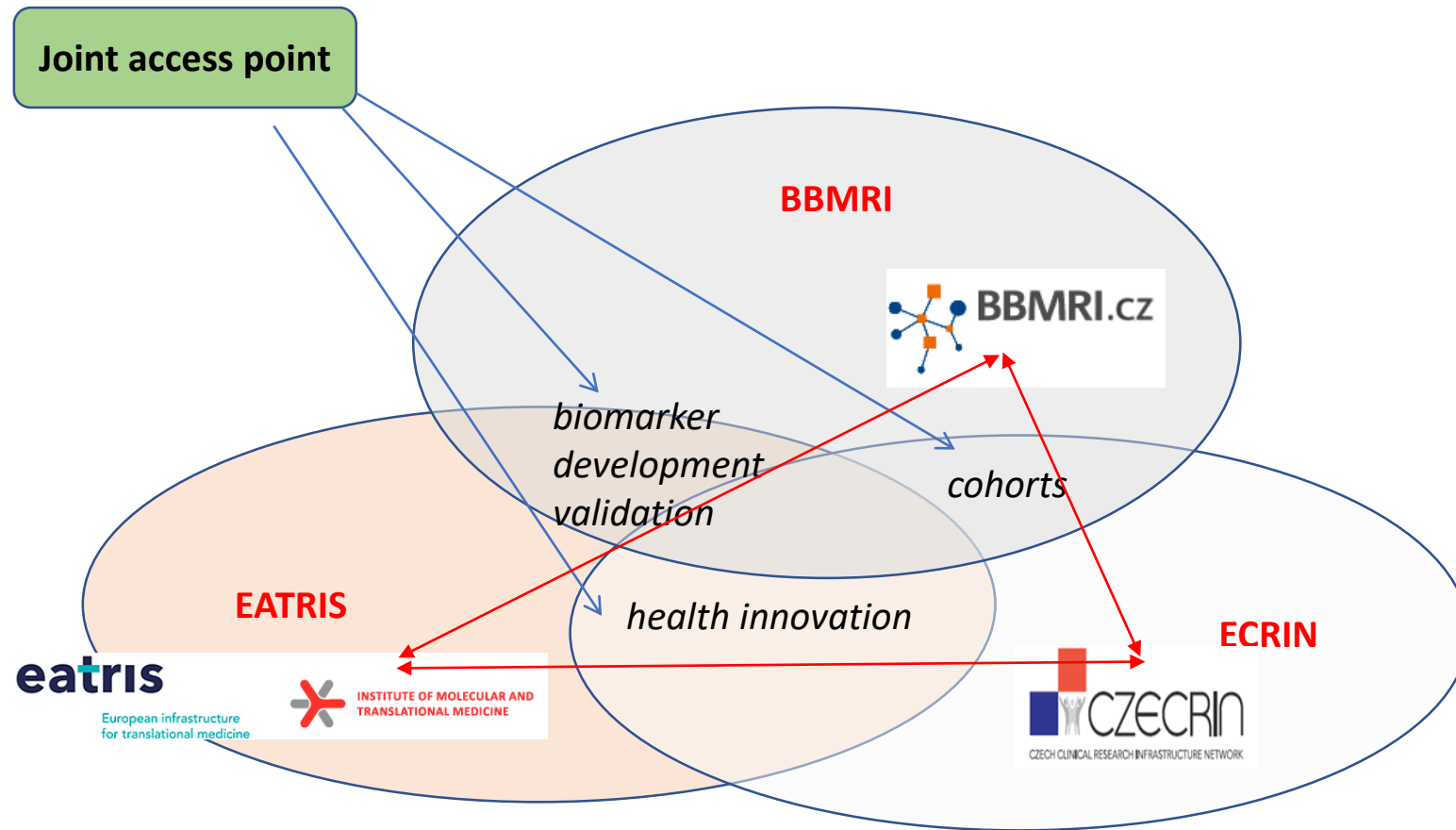
Research networks

Investigators networks

Patients' registries

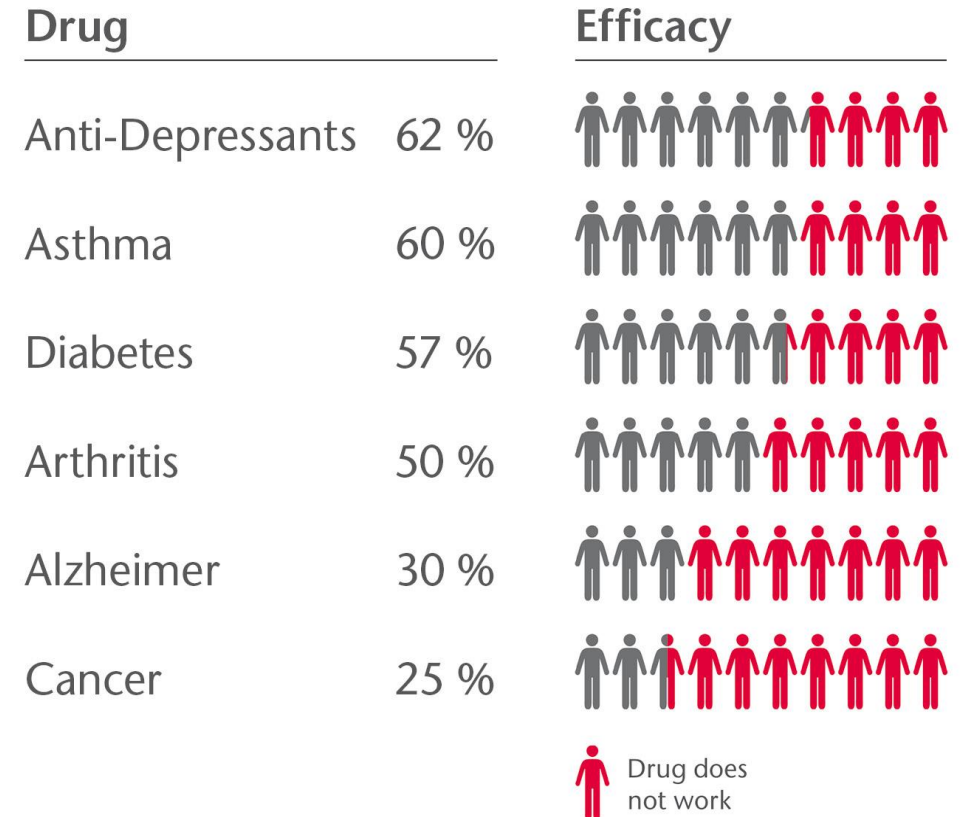


Cooperation of medical research infrastructures



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),

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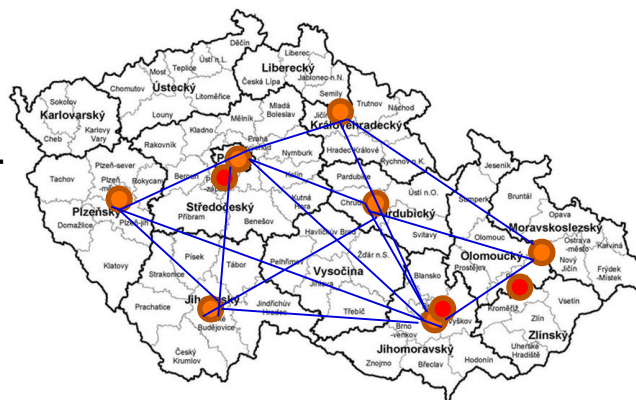
- In operation phase since March 2014
- Included in Roadmap for Large Research, Development and Innovation Infrastructures in the Czech Republic
- Under responsibility of with Ministry of Education, Youth and Sport
- Budgeted till 12/ 2019 (approved for 2020-2022)



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



... 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 Palacký University Olomouc
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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

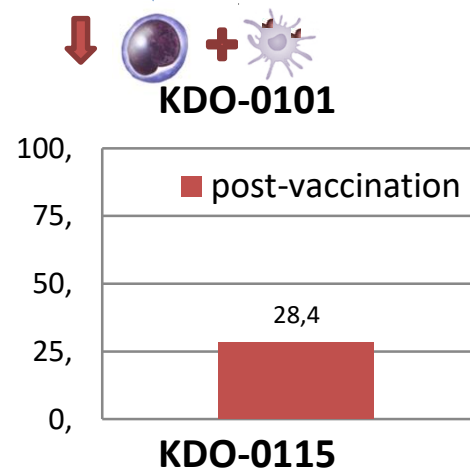
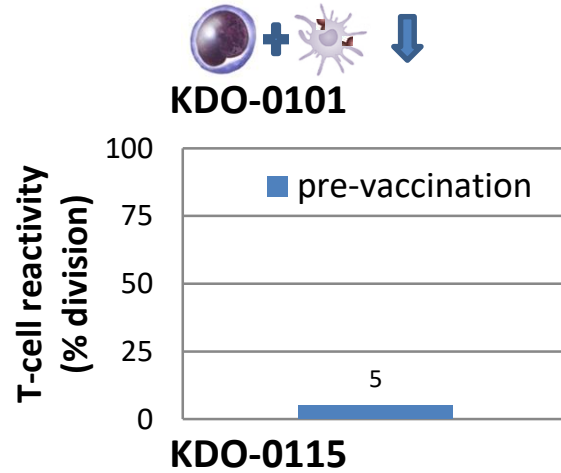
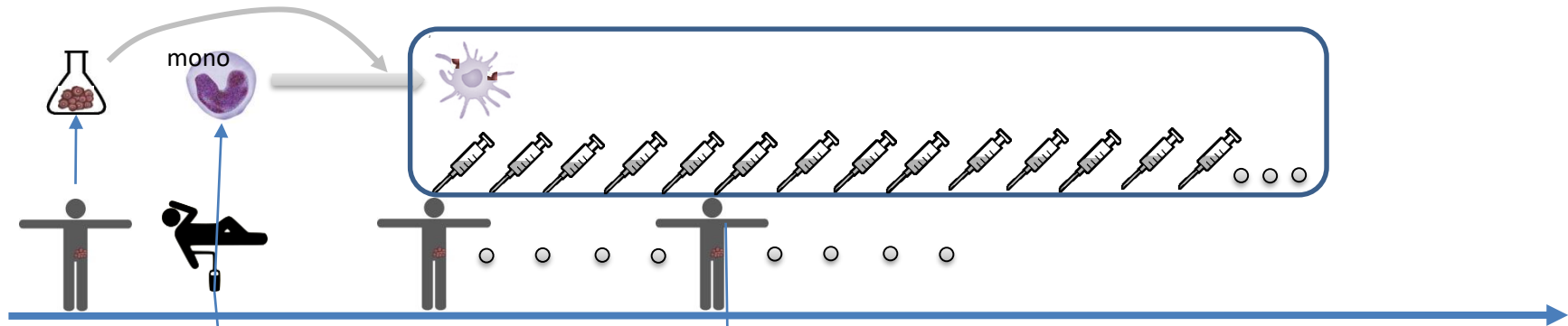
Farmakologický ústav LF MU, Advanced
Cell Immunotherapy Unit

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



European network of paediatric research
at the European Medicines Agency



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 !!

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

N- of-1 clinical trials...

Learn from every patients – not just clinical trial patients !

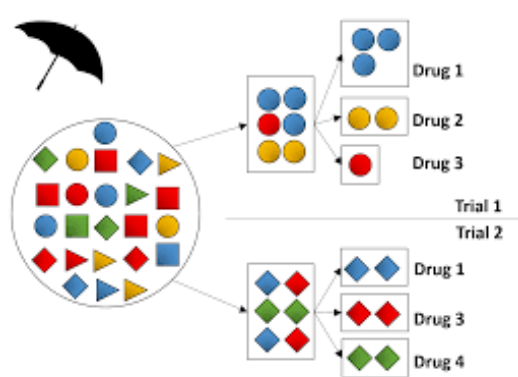


Figure 2: Umbrella trial based on histology and genotype

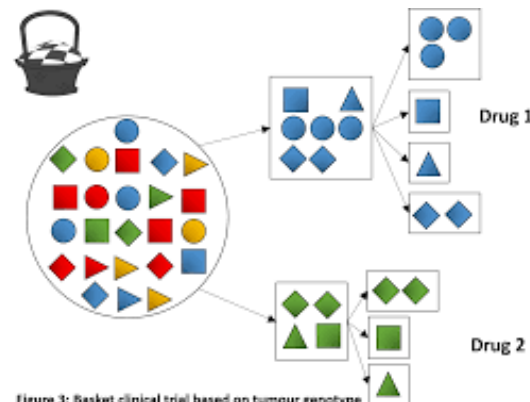


Figure 3: Basket clinical trial based on tumour genotype

CZECRIN Clinical Trials



RCC_DC
-2011

CZECH-
ICIT

MEMMAT
TIGER

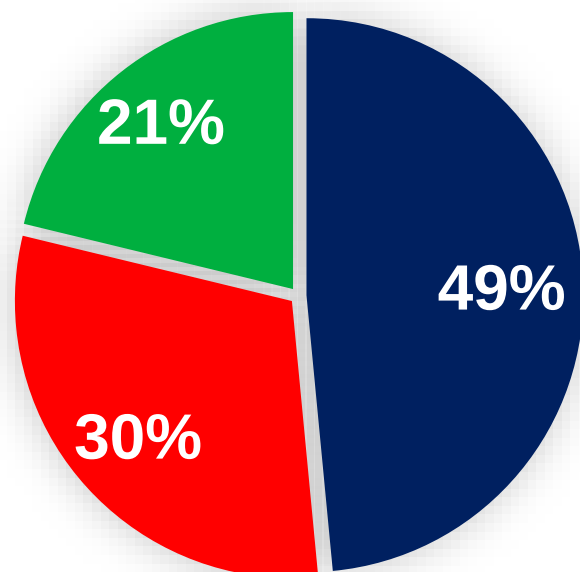
Dauno
Double
PNET 5

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

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

