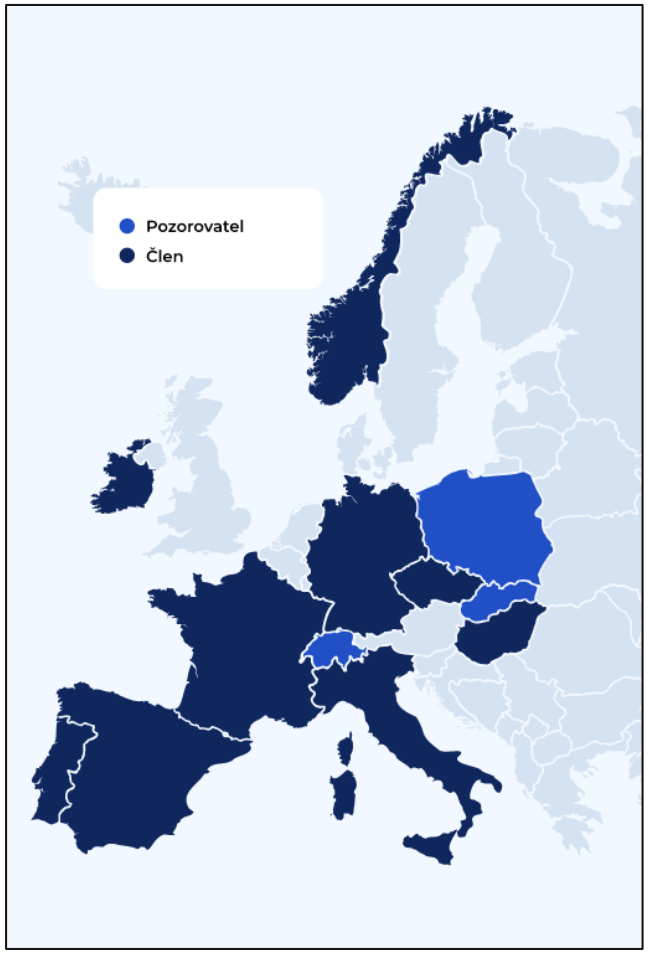
CZECRIN
a oborově orientované sítě

Regina Demlová, LF MU Brno

CZECRIN
CZECH CLINICAL RESEARCH INFRASTRUCTURE NETWORK

MUNI MED

FNUSA ICRC
FAKULTNÍ NEMOCNICE U SV. ANNY V BRNĚ
MEZINÁRODNÍ CENTRUM KLINICKÉHO VÝZKUMU



- CZECRIN je klíčovou infrastrukturou podporující od roku 2014 realizaci nekomerčního klinického výzkumu v České republice
- Od ledna 2018 je ČR plným členem evropské sítě ECRIN-ERIC
- Jako český uzel Evropské sítě infrastruktur klinického výzkumu ECRIN-ERIC zásadním způsobem přispívá k zapojení akademických institucí do mezinárodních projektů klinického výzkumu
- CZECRIN disponuje unikátní sítí zahrnující většinu významných klinických pracovišť s orientací na klinický výzkum a poskytuje znalostní, vývojové, výrobní a implementační kapacity v oblasti výzkumu a vývoje léčiv zdravotnických prostředků; nastavuje kvalitu procesů dat s ohledem na aplikaci FAIR principů a je rovněž centrem pro kultivaci a edukaci v oblasti KS

CZECRIN IDENTITA

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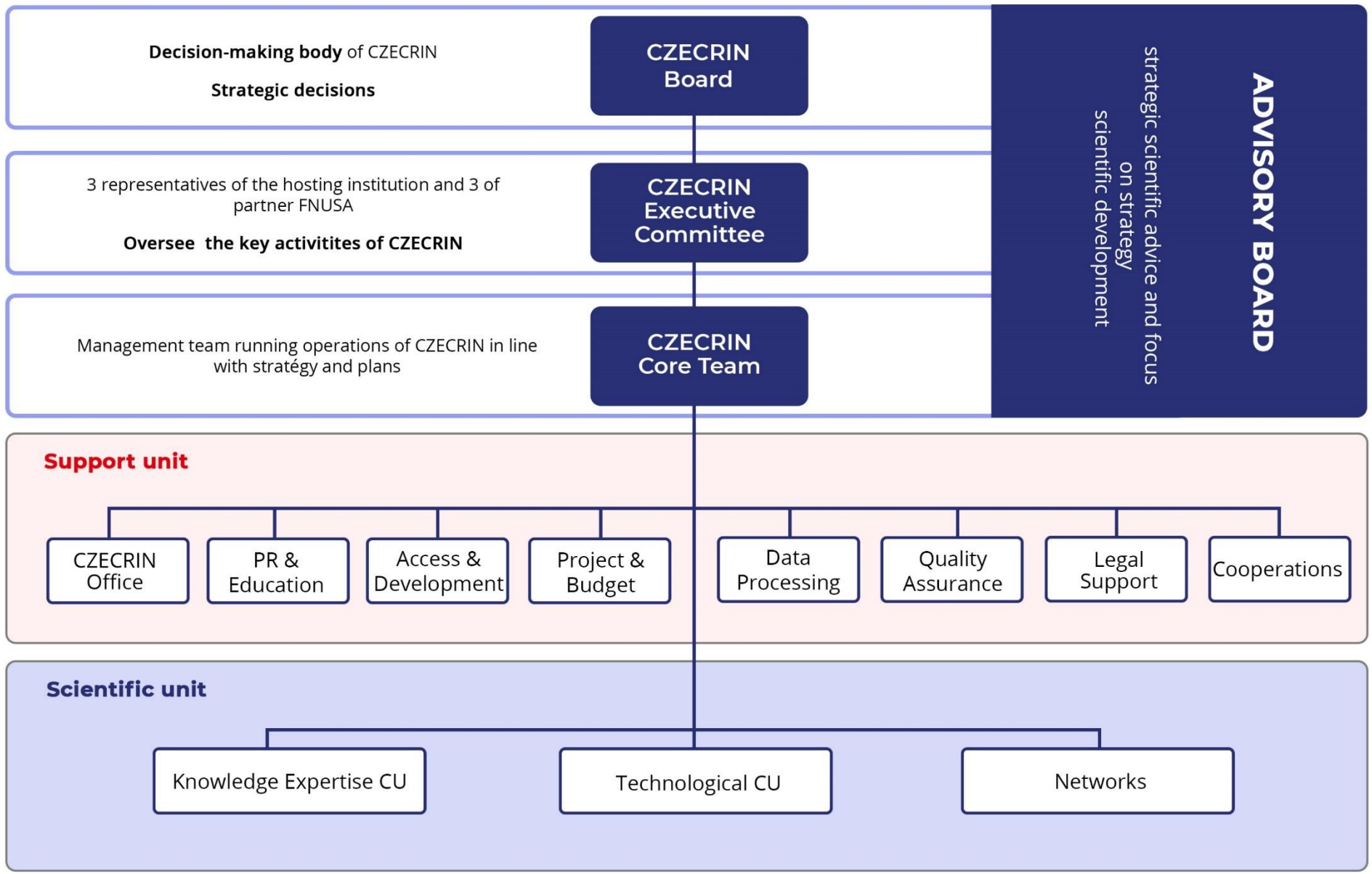
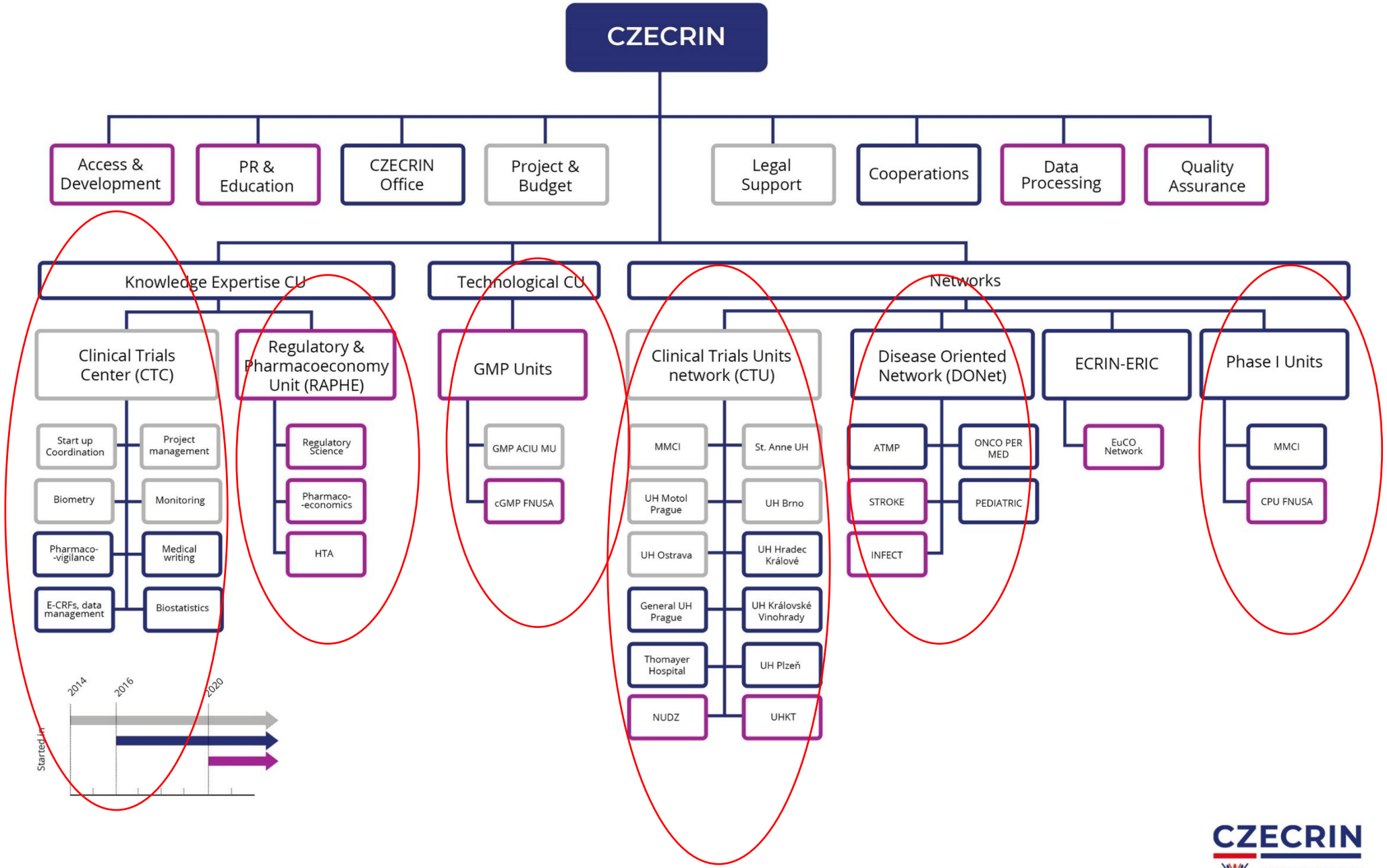
CZECRIN GOVERNANCE STRUCTURE



Annex 6: CZECRIN ORGANIZATION CHART 2020



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Annex 1: CZECRIN main services

Where the research idea and investigators come from?

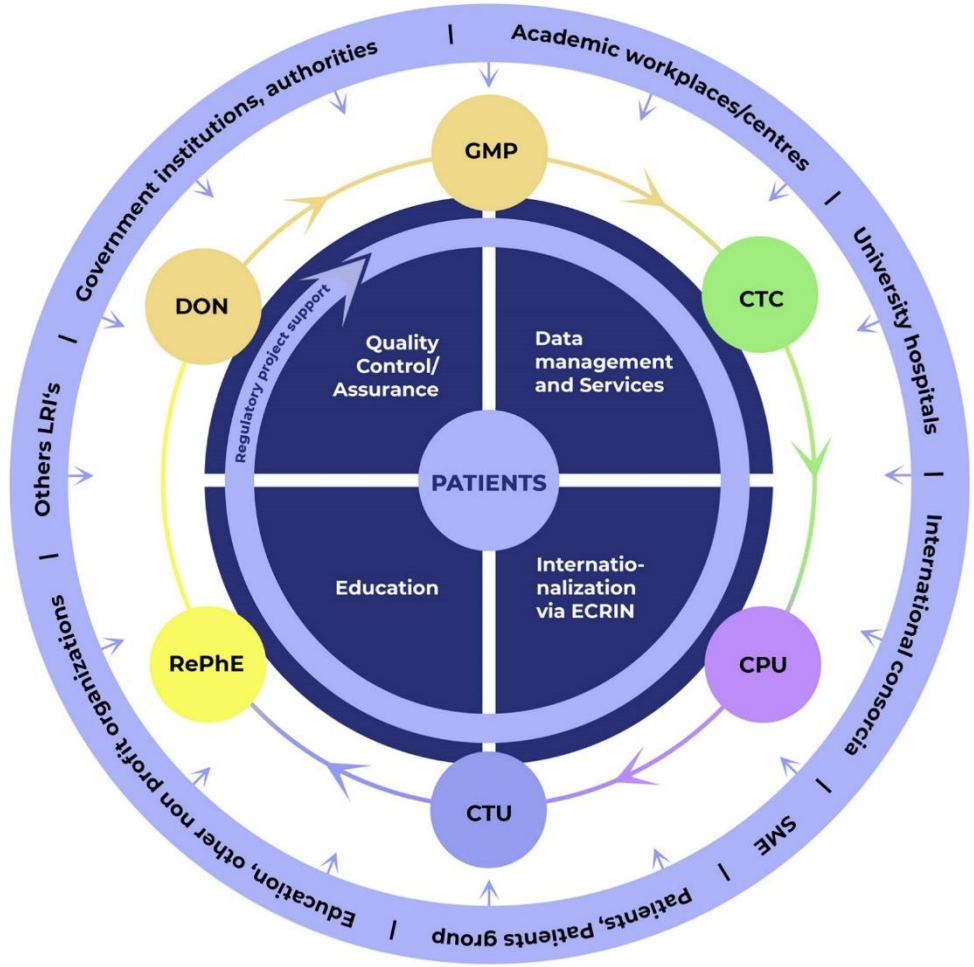
Where can be the investigational medicinal product developed and manufactured?

How to ensure the regulatory and legislative requirements for clinical research?

Where can be realized the phase I trials with healthy volunteers?

How to get direct access to clinical trial participants and local ECs?

Where to find regulatory advice and pharmacoeconomic assessment?



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CZECRIN Clinical trials/studies Initiated each respective year / user category

User Category	2014-2015	2016	2017	2018	2019	2020*/
University Hospital	9	11	14	28	37	90
Internat. Consortia	1	3	7	12	21	30
Academic Center	0	3	6	8	18	21
SME	0	0	0	1	3	8
Other LRI	0	0	1	1	1	4
Gov/authority/WHO	0	0	0	0	0	2
TOTAL	**10**	**17**	**28**	**50**	**80**	**125**

*/ until October 2020

Disease-Oriented Network

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Oborově orientované sítě pro nekomerční klinický výzkum

- Napříč jednotlivými diagnózami a medicínskými obory jsou v souladu se strategií CZECRIN, nejnovějšími trendy a vědeckými poznatky definovány prioritní oblasti klinického výzkumu
- V těchto oblastech/výzkumných směrech jsou pod vedením renomovaných klinických expertů budovány oborově orientované sítě (DONet) spolupracujících zdravotnických pracovišť a zapojených lékařů spolupracujících s koordinátory klinických studií CZECRIN
- Sítě sdružené v DONet sdílejí podpůrné a odborné kapacity CZECRIN a úzce spolupracují s ostatními sítěmi

CZECRIN STROKE

Czech sroke Research Network

The complex development and implementation network of innovative methods for the evaluation, treatment, and prevention of acute ischemic stroke. Research portfolio is designed vertically across the spectrum from basic science to clinical research and networking.

CZECRIN$_{STROKE}$ promotes translational approach so that knowledge gained through basic research is applied and tested in clinical practice to benefit patients and improve outcome after stroke.

The main research topic of the CZECRIN Stroke program is development of new diagnostic and therapeutic algorithms for stroke. The CZECRIN Stroke program pioneered the administration of thrombolytic therapy in the Czech Republic (since 1998). Currently, the CZECRIN Stroke Center treats about 800 stroke patients per year, with approximately 100 patients receiving i.v. thrombolysis every year. Using modern technologies, we ensure to provide appropriate acute and preventive stroke care. The Stroke program is one of the most active contributors in the SITS Registry in the Czech Republic. Moreover, the Stroke program is a leader of the SITS-EAST, the most active regional network (in Central and Eastern Europe) within SITS International.

EXPERTISE

- Research on implementation of evidence-based treatments
- Development of in vitro and animal model for stroke to test new diagnostics (e.g. basic thrombus imaging) and therapeutic strategies (e.g. new racanalization methods)
- Identification of better stroke awareness methods including program on stroke awareness in children.

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info@czecrin.cz

ACTIVITIES

- Simulation training and methodology- is intended for stroke teams and professionals in stroke
- System Engineering/Software Developing and data management
- Preclinical Research: highly sophisticated in vitro flow models and small animal models of stroke
- Web-based platform for education of children and lay public in Stroke
- Coordination of clinical trials

Network partners and international collaborations

National coordinator: St. Anne´s University Hospital Brno

Leading expert: prof. MUDr. Robert Mikulík, Ph.D

Institutional partners:

- St. Anne´s University Hospital Brno
- University Hospital Brno
- Hospital Na Homolce
- University Hospital Motol
- Military University Hospital Prague
- University Hospital Ostrava
- Regional Hospital Liberec
- University Hospital Olomouc
- Hospital České Budějovice
- University Hospital Hradec Králové
- Hospital Vyškov
- University Hospital Královské Vinohrady
- General University Hospital Prague
- Thomayer´s hospital Prague
- Hospital Jihlava
- Mining hospital Karviná
- Hospital Písek
- Regional hospital Tomáš Baťa
- Hospital Pradubice

International Cooperation:

- European Stroke Organisation, Switzerland
- ANGELS Initative, The world-wide stroke support project, Germany
- University of Calgary, Canada
- Network of Stroke Centres in Central and Eastern Europe
- GAINS, The Global Alliance of Independent Networks focused on Stroke Trials

CZECRIN is a key national functional infrastructure facilitating academic clinical research in the Czech Republic. CZECRIN as a national node of the European infrastructure ECRIN-ERIC represents also direct connection with European Research Area, which is crucial for development of the Czech clinical research for the benefit of global public health. CZECRIN has a unique network covering major clinical sites and provides the knowledge, development, production and implementation capacities in the field of medical sciences. Sets the quality of processes and data based on the application of FAIR principles. CZECRIN is also a center for education in the field of clinical trials.

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CZECRIN ATMP

Czech National Network for Advanced Therapy Medicinal Products

The network of CZECRIN GMP facilities makes it possible to develop, produce, and finally administer ATMPs (Advanced Therapy Medicinal Products), e.g. somatostatic cell or gene therapies or engineered medical products. In established clinical sites, including a network of CZECRIN Phase I Units, should the ATMP be evaluated for safety and efficacy.

CZECRIN ATMP's mission is to promote and conduct excellent clinical science and research in the area of advanced therapies

Advanced Therapy Medicinal Products (ATMPs) are medicines for human use with an active therapeutic substance based on at least one of the following;

- Technology to modify the patient genome
- Recombinant nucleic acids or genes
- Substantially manipulated cells
- Cells intended for a different essential function in the patient versus the donor
- Engineered tissues

GMP Units represent excellent non-commercial production units for advanced therapy medicinal products (ATMP), including dendritic cells (DB), activated expanded lymphocytes (AEL), mesenchymal stromal cells (MSC), or CAR-T cells. GMP units are approved by the National Regulatory Agency. All manufacturing and production-control activities are carried out in accordance with the principles of Good Manufacturing Practice (GMP Quality), to the extent of the authorization for the manufacturer of investigational medicinal products within the clinical trial. GMP Units are a quite unique facility within the academic sector and in combination with the "Knowledge Expertise Core Unit" of LRI CZECRIN, it allows to improve the effective translation of academic discoveries to further clinical steps

The impact of usage of the Advanced Therapy Medicinal Products has two basic dimensions. The first one is a group of experts in clinical applications as well as research in the given field. This group will be able to produce relevant projects of good quality in the frame of the clinical application. It will increase the availability of up-to-date information about the Advanced Therapy Medicinal Products in the Czech Republic and further reinforce the team's competitiveness on the European level and globally. The second dimension is the outstanding importance resulting from using the safe Advanced Therapy Medicinal Products that is tailored-fit for a particular patient who can directly benefit from that new treatment method.

EXPERTISE

- Medical expertise in ATMP medical products
- Manufacturing of viable autologous, allogeneic or xenogeneic cells
- Manufacturing and production control activities in CTEF, carried out in accordance with the principles of cGMP quality
- Scientific expertise in ATMP area
- A national network of GMP Units in CZ

ACTIVITIES

- To promote non-commercial clinical trials with ATMP products
- To disseminate knowledge and organize educational activities in this field
- To support the development of national and multinational academic projects.
- To establish a single point of contact for ATMP international trials and to facilitate their implementation among Czech centers.
- To participate in European and international perinatal research programs
- To promote competitive clinical science and academic research.
- To guarantee excellence in good clinical practice and quality assurance in ATMP trials

Network partners and international collaborations

National coordinator: Masaryk University

Leading expert: Assoc. Prof. Lenka Zdrazilova Dubska, PhD

Institutional partners:

- GMP Unit – ACIU LF MU, Brno
- CTEF-cGMP FNUSA-ICRC, Brno
- GMP, University Hospital, Pilsen
- GMP, Institute for Blood and Transfusion, Prag

International Cooperation:

- EATRIS-ERIC
- ICPerMed
- Karolinska Institute
- Univerzity of Heidelberg

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Další rozvoj oborově orientovaných sítí pro klinický výzkum

CARDIO NETWORK
LEADING INSTITUTION: FN Královské Vinohrady

ONCOLOGY NETWORK
LEADING INSTITUTION: Masarykův onkologický ústav

EPILEPSY NETWORK:
LEADING INSTITUTION: FN u sv. Anny v Brně

PSYCHIATRY NETWORK:
LEADING INSTITUTION: Národní ústav duševního zdraví

- Podpora nekomerčních klinických studií a projektů klinického výzkumu s dopadem do reálné léčby pacientů
- Participace v mezinárodních grantových schématech
- Nastavení QA/QC v oblastech klinického výzkumu
- Podpora mladých výzkumně orientovaných lékařů
- Finanční podpora CZECRIN pro ustavení sítě studijních koordinátorů v rámci jednotlivých sítí

SPOLUPRÁCE

- Nabízíme svou expertízu a komplexní služby pro realizaci klinického výzkumu v České republice
- Spuštěním nových webových stránek jsme usnadnili přístup ke spolupráci na realizaci klinického výzkumu
- Nové stránky nabízí také komplexní informace o expertíze CZECRIN a tím podávají také jasnou informaci o tom, jak může CZECRIN pomoci v realizaci konkrétního projektu
- www.czecrin.cz