

Clinical Research Units (CRU)

GLOBAL Network



CRU GLOBAL RESEARCH NETWORK

Clinical centres:

- Hungary (1 Early Phase Unit, 3 Later Phase Unit, 2 Outpatient Clinic)
 - Germany (1 Later Phase Unit, 1 Oncology Outpatient Clinic)
 - Ukraine (1 Early Phase Unit, 1 Later Phase Unit, 1 Outpatient Clinic)
 - Vietnam (1 Early Phase Unit, 1 Later Phase Unit, 1 Outpatient Clinic)
- Further openings in 2020: 1 Phase I Unit in Germany and 1 Early phase and 1 later Phase Unit in South-East Asia



CRU HUNGARY EPU

- The first and still the biggest CRU Global Research Unit
- The biggest accredited Phase I center in Hungary
- The only private Clinical Center approved in Hungary for Oncology studies
- Over 200 completed clinical studies in the last 5 years
- Worldwide top enroler in many indications
- Preferred partner for the biggest Pharma and CRO companies
- Well trained, highly dedicated, full-time professional staff (37 person)
- State-of-the-art infrastructure
- All diagnostic tools are available in-house
- Full-time intensive care background
- Located within one of the biggest hospital
- An accredited teaching site



AREA OF STUDIES in CRU Hungary

- pulmonology
- cardiology
- diabetology
- rheumatology
- dermatology
- neurology
- oncology
- gastroenterology
- gynecology



Currently (02Dec2019):

- 33 recruiting studies
- 24 ongoing studies
- 13 to start studies
- 31 feasibility studies
- 877 active patients

Clinical Research In Hungary



- Significant history of Clinical Research
- One of the TOP 3 country within Europe (based on the number of studies/population and quality metrics)
- ICH-GCP and EU-harmonized regulations are fully implemented
- Good regulatory timelines and only a 1 step process
- Dedicated, highly qualified research staff
- Population is only 10 million people, but:
 - Many trial-naiv patient (especially in the countryside)
 - Worldwide top incidence in many indications/diseases
 - The best patient register on the world due to the social insurance system



High quality, top performance on a more affordable price

CRU Clinical Research In Hungary

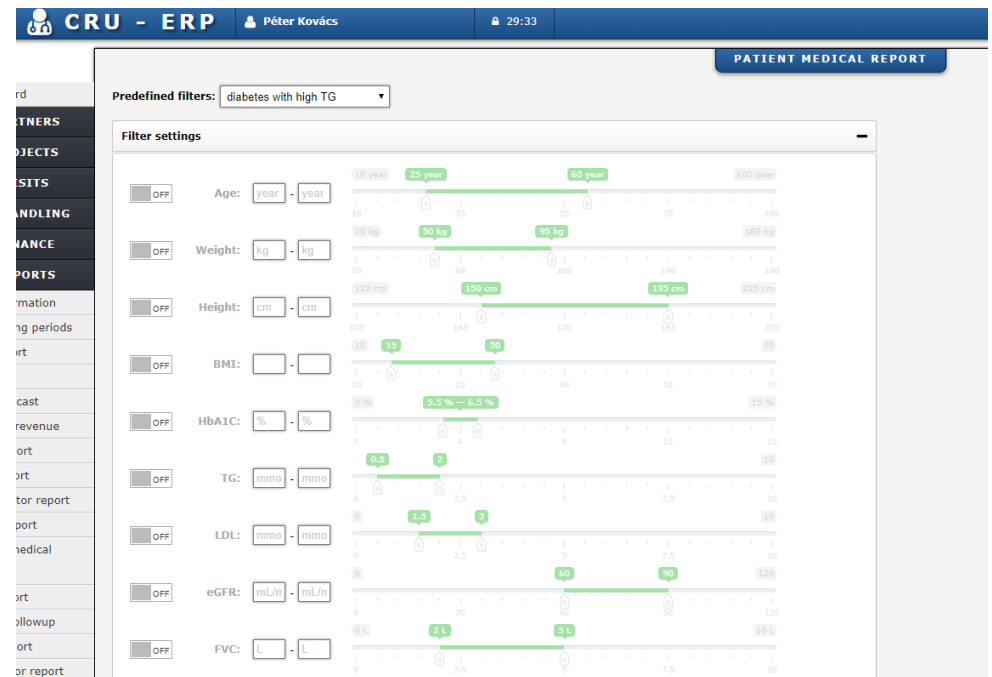


- 3 dedicated sites in Hungary
- The main site (with Phase I unit) is in Miskolc with a catchment area of 1,2 million population
- The other 2 sites with a catchment area of 6-800,000 people



Patient pool

- Continuously expanding filterable subject **database** (approx. 6000 subjects) in most common indications with full medical history
- Hospital catchment area is: 1,2 million people!
- Extensive **GP network**
- Interaction with other healthcare institutes
- **Specialist** referrals
- **Own public health services**
- External recruiting services



Quality management

- Full time employed Quality Management
- SOPs, uniform processes applied
- Calibrated instruments, validated processes
- Continuous internal training for clinical staff
- 34 Sponsor/CRO audits
- No critical/major findings
- Regulatory inspections:
 - NIP – 2009, 2015, 2018
 - FDA 2017, 2018: NAI!

This inspection was conducted as a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to help ensure that the rights, safety, and welfare of the human subjects have been protected.

We have reviewed the FDA Establishment Inspection Report and the documents submitted with that report, and we did not identify any objectionable conditions or practices that would justify enforcement action by the Office of Compliance.

No response to this letter is necessary. However, if you have any questions or concerns about this letter or the inspection, please write to me at the address given below.

Sincerely,

{See appended electronic signature page}

CDR LaKisha Williams, USPHS
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Division of Clinical Compliance Evaluation
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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