

New Voxel Innovation Campus - challenges and perspectives for polish radiopharmaceutical community

Marek Pilch-Kowalczyk

VOXEL S.A
ul. Ceglana 35,
40-514 Katowice, Poland
mpk@voxel.pl



Fundusze
Europejskie
Program Regionalny



Rzeczpospolita
Polska

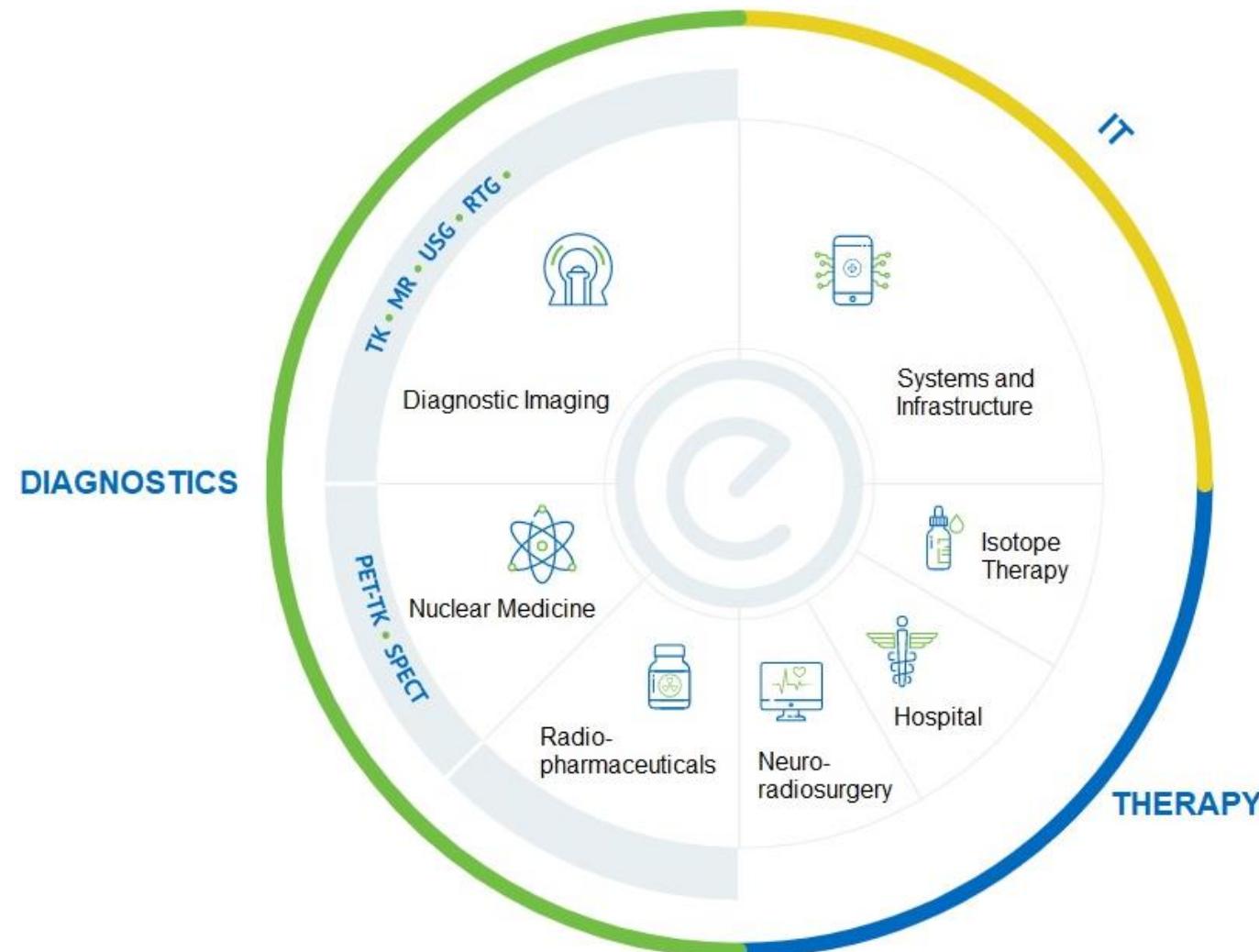


MAŁOPOLSKA

Unia Europejska
Europejski Fundusz
Rozwoju Regionalnego



Voxel Group



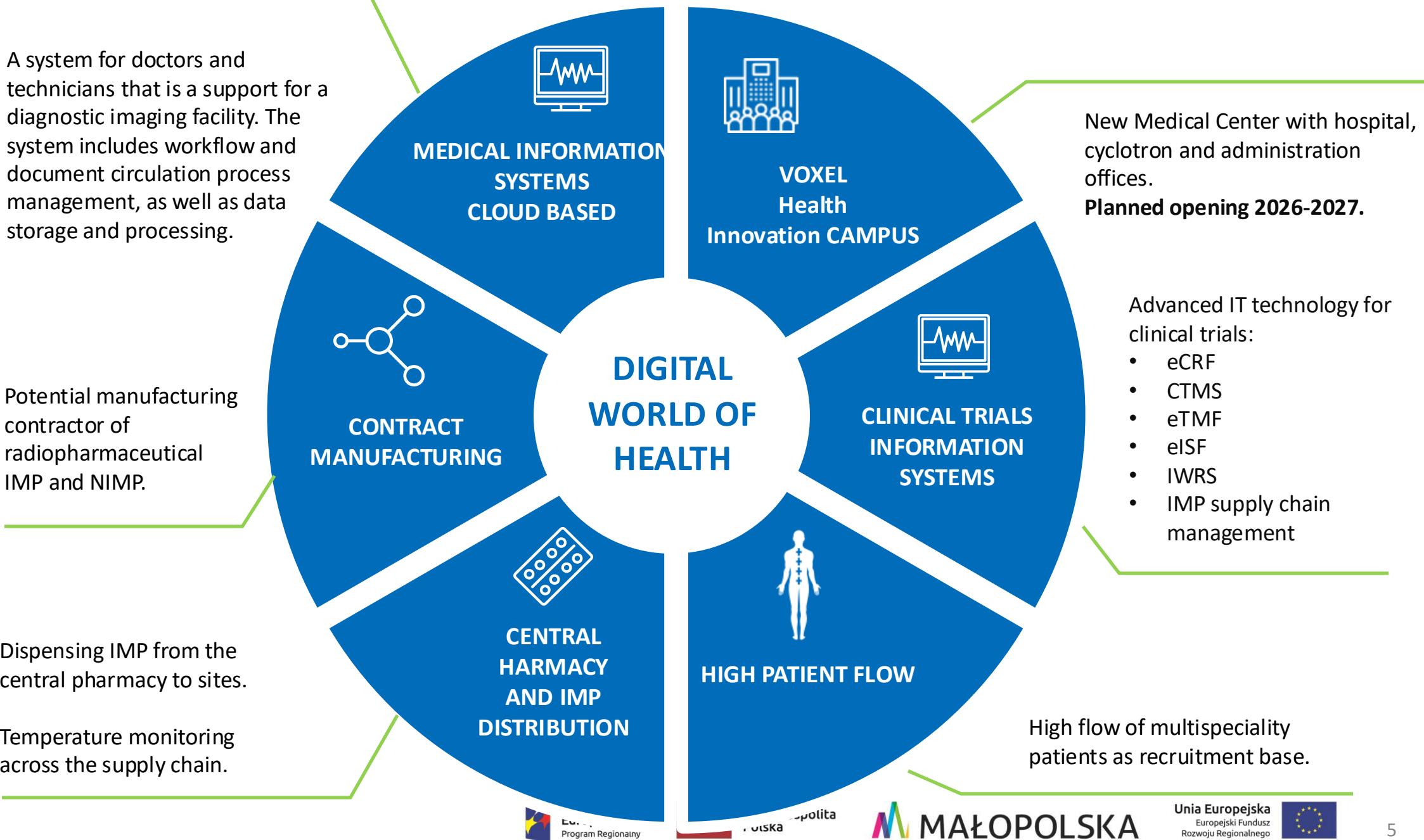
VOXEL Group key numbers

- 44 diagnostic centers
- 66 scanners
 - including 7 PET/CT scanners
- Cover 14 voivodships
- Over 400 radiologists and 22 nuclear medicine specialists
- 282000 MRI exams in 2024
- 135000 CT exams in 2024
- 19000 PET/CT exams in 2024
- 18000 SPECT exams in 2024

Production and distribution of radiopharmaceuticals

- **3 GMP-compliant facilities** equipped with in-house microbiology and sterility/bioburden-certified laboratories, also supporting third-party projects. Current production includes ^{18}F , ^{11}C , ^{64}Cu , ^{89}Zr , and ^{68}Ga
- The centers are prepared to initiate production of other off-site isotopes, including ^{131}I and ^{21}At , building on the experience of specialists from other leading facilities
- Sites located in **Warsaw, Krakow, and Katowice** – with **Katowice being the newest and most advanced facility, purpose-built to expand CDMO capabilities**
- Modern synthesis modules and state-of-the-art cleanrooms equipped with systems from **GE Healthcare, Comecer, and Trasis**





Manufacturing of PET radiopharmaceuticals in own cyclotrons

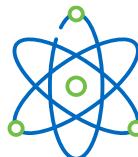
MAH



V-PET, FCH,

V-NaF, V-

Ga68



R&D projects Funded by EU and
Medical Research Agency grants

GMP Manufacturer



Radelumin (^{18}F -PSMA)



Pharmaceutical
Distributor

Radiopharmaceutical
Production Center
Warsaw

Radiopharmaceutical
Production Center
Krakow

Voxel
Health Innovation CAMPUS Katowice
Work in progress



Fundusze
Europejskie
Program Regionalny



Rzeczypospolita
Polska



MAŁOPOLSKA

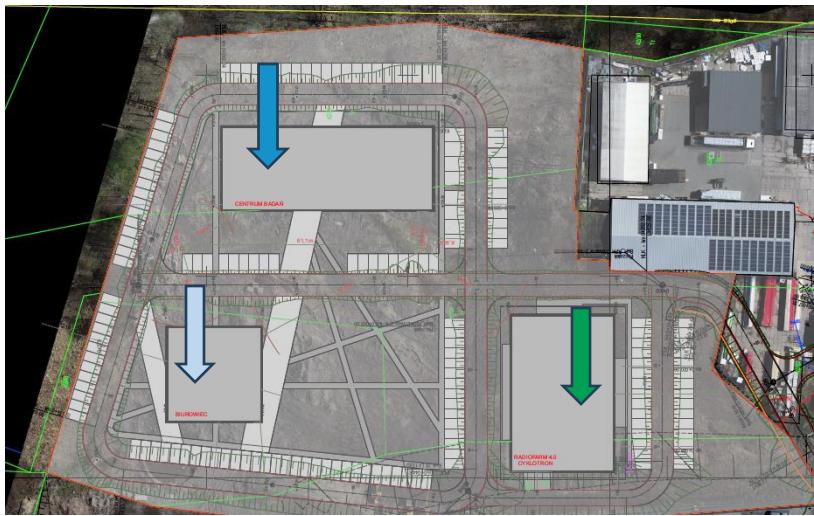
Unia Europejska
Europejski Fundusz
Rozwoju Regionalnego



Alteris Radiopharmaceutical Production Center

Clinical Center PET/CT, MRI, NM, Genetics,
Theranostic

Voxel Group Headquarters Offices

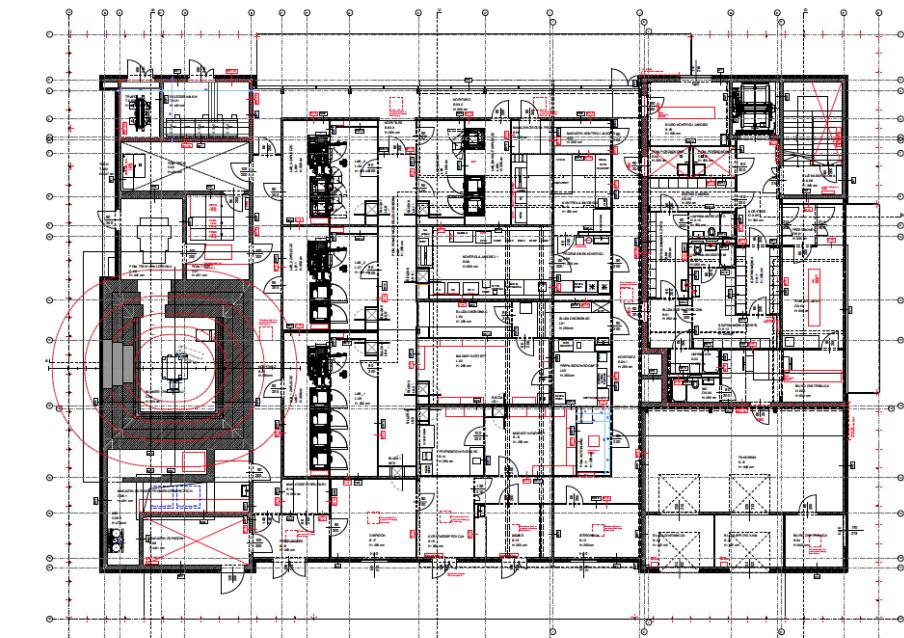


STEP 1 OPERATIONAL 2026

STEP 2 OPERATIONAL 2027



Fundusze
Europejskie
Program Regionalny



Katowice – New CDMO Site Overview

- **Total area:** 1 985.2 m², Laboratories: 263.2 m², Microbiology: 165.5 m²
- **GE PETtrace 890 cyclotron** installed in a dedicated bunker
- **4 clean rooms**, including one **R&D suite**
- **Hot cells:**
 - Lab 1: 2x BBS2-H
 - Lab 2: 1x BBS2-H
 - Lab 3: 1x BBS2-V + space for additional BBS2-V
- **Dispensing units:** one **Comecer Theodorico 2** per clean room (each with autoclave) or manual adaptation of dispensing (Musa Comecer)
- **Capability for aseptic processing and final sterilization production**
- **2 Quality Control laboratories** equipped for full analytical testing
- **Analytical instrumentation:**
 - 2x GC Agilent, 2x HPLC Agilent, HPGe Gamma spectrometer DSA-LX, Canberra
 - TLC scanner Scan-RAM 2 (LabLogic), LAL testing system nexgen-PTS (Charles River Endosafe), 2x HPLC Perkin-Elmer with DAD detector



Strategic Location and Certified Logistics

- Strategically positioned near two international airports:

Katowice Airport (Pyrzowice) - 35 km / 30 min

Kraków Airport (Balice) - 80 km / 50 min

- Excellent access to major road networks (A4 and S1)
- **Own transport fleet** for radiopharmaceutical deliveries
- Operated as **privileged transport units, blue lights**
- Ensuring **fast, secure, and compliant distribution**
- **Easy and rapid air shipment available to any global destination**

Commercialization, Patents & Registrations

Patents & Publications

2024 - Patent application: *Cassette and method for Gallium-68 isotope purification* (P.450317)

Publication: *Evaluation of Cyclotron Solid Target Produced Gallium-68 Chloride for the Labeling of [⁶⁸Ga]Ga-PSMA-11 and [⁶⁸Ga]Ga-DOTATOC*, *Molecules*, DOI: 10.3390/molecules30173458

Products Registrations (MAH)

2016 – Cholina Weglowa (Choline¹¹C) – delisted in 2023

2018 – V-PET (Fludeoxyglucose ¹⁸F)

2020 – FCH (Fluorocholine ¹⁸F)

2023 – V-Ga68 (Gallium ⁶⁸Ga chloride solution)

2024 – V-NaF (Na¹⁸F solution)

Licensing & Technology Transfer

2013 – SteriPET (GE Healthcare MAH)

2025 – PSMA-1007 (ABX MAH)

2025 – rhPSMA7.3 (BED MAH) – on going

Cu-64, Zr-89 for Life Science

Zr-89 :

- $T_{1/2}=3,3$ d
- Ideal isotope for dynamic studies of peptides and proteins
- 2 weeks of follow up after single injection

Cu-64 :

- $T_{1/2}=12,9$ h
- Starting clinical trial
- Planned to MA in 2026

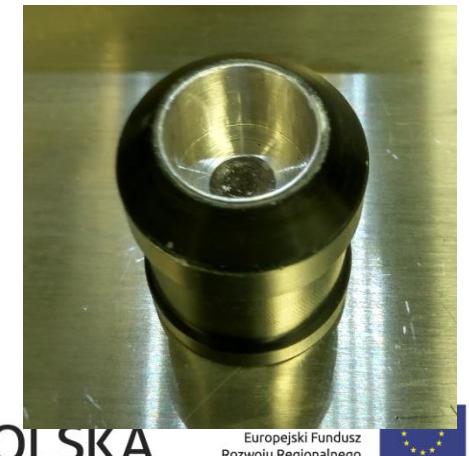


Image Acquisition, PACS & VNA
CLOUD BASED

Central teleradiology and double reading
(quality control)

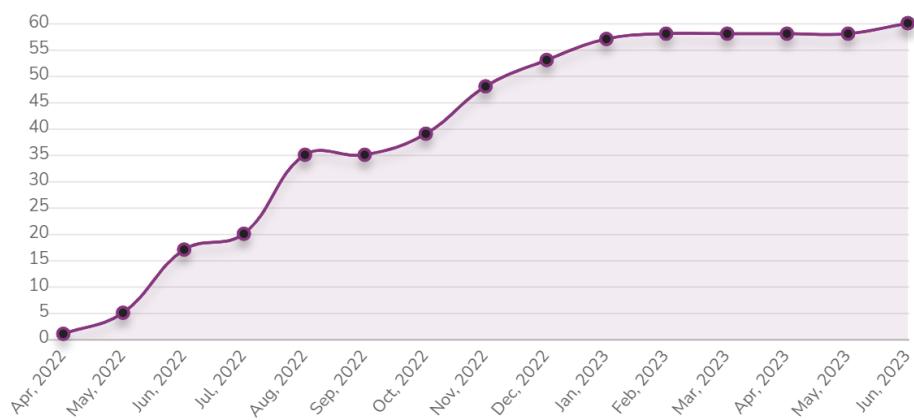
Clinical trial DICOM storage
Image Sharing & Reporting Workflow

Data security based on blockchain
Patent protection EPO and USA
Us 11,985,227 b2
Ep3945704a1



- Digital Source Data
- CTMS
- EDC
- eTMF
- eISF
- IWRs
- IMP Distribution System

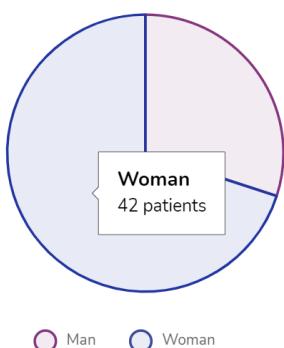
Number of patients over time



Patients status

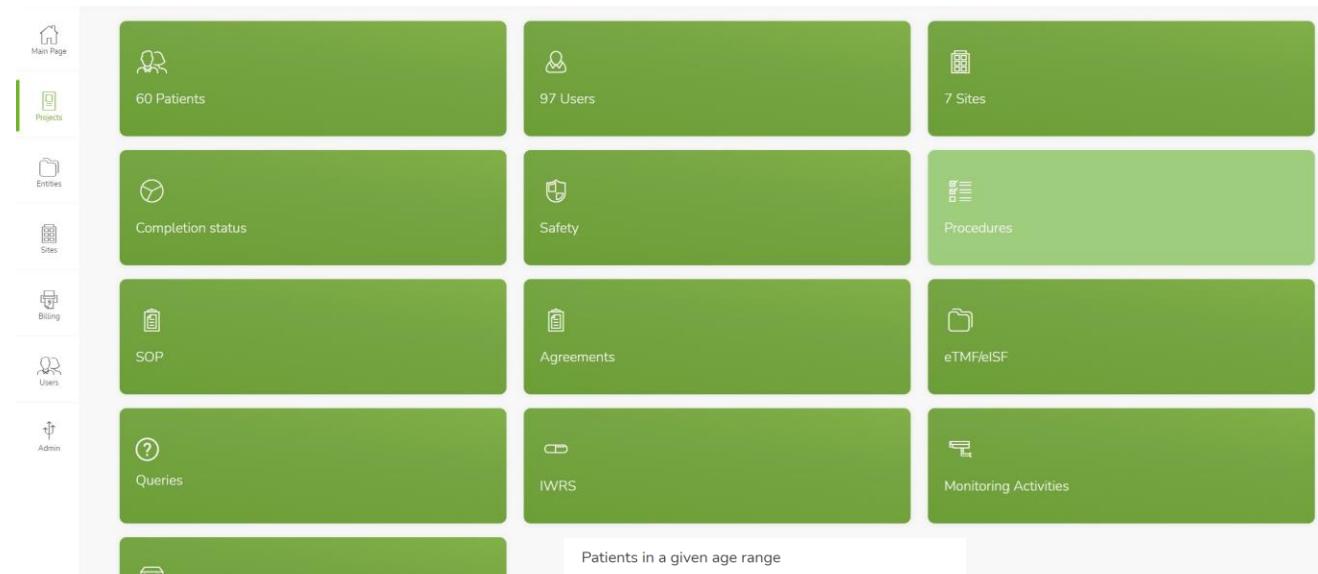


Gender distribution



Remote Monitoring Tools

Data Management Department



Models of cooperation

- Subcontractor of scientific grant
- Industry partner for european grants
- Contract manufacturer of radiopharmaceuticals for clinical trials
- Partner for clinical studies involving the diagnostic imaging and nuclear medicine
- Training center for radiopharmacy and nuclear medicine
- Source of radioisotopes ^{18}F , ^{64}Cu , ^{89}Zr

Scientific and Technical Expertise

- **17 chemists, 5 physicists, 4 biochemists**, supported by a skilled group of technical personnel, radiation safety inspectors, and certified ADR drivers (over 40 people)
- Chemists with extensive experience in aseptic radiopharmaceutical production under GMP conditions. 2 team members have completed training at **ETH Zurich (Module II: Radiopharmaceutical Chemistry)**, and one holds a **CAS in Radiopharmaceutical Chemistry/Radiopharmacy**
- **Dynamic team of young PhDs**, highly motivated, engaged, and ready to take on new challenges in radiopharmacy and CDMO projects
- **Strong collaboration** with universities and R&D centers to foster innovation and technology transfer
- **Pilot projects** continuously expanding our internal know-how and production capabilities
- **Experienced management team** with corporate backgrounds and serial entrepreneurs providing strategic direction and mentoring



Thanks for your attention
Questions are welcome

Marek Pilch-Kowalczyk
mpk@voxel.pl +48 697700071