The Krakow proton therapy facility, lessons learnt

- the Cyclotron Centre Bronowice project at the Institute of Nuclear Physics

Pawel Olko
Institute of Nuclear Physics IFJ PAN, Kraków, Poland

Cyclotron Centre Bronowice: from the first proposal to the first patient (2006–2016)

Poland joint EU

First proposal to OP IE failed

Proposals for CCB and gantry – failed

Contract with Min. Science for CCB- 1st phase

Contract with Min. Science for gantry

Installation of C-235 cyclotron May 2012

Gantry 1 operational

Gantry 2 operational

2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017

First promise from Min. science for 25 MEuro

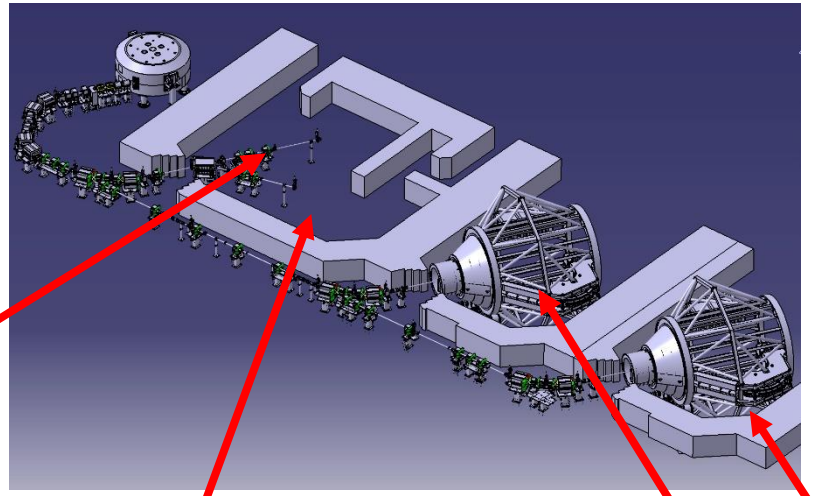
Signing contract with IBA 08.2010

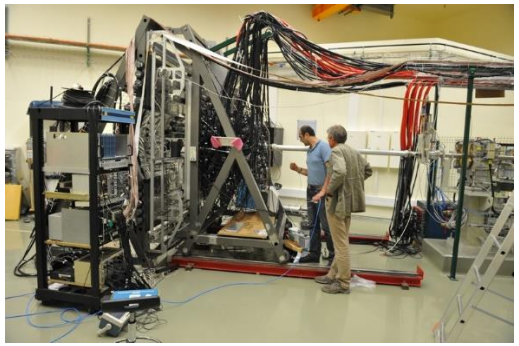
Bulding completed

First patient February 2016

What was built ?

IBA C-230 cyclotron





experimental room

eye treatment

2 scanning gantries

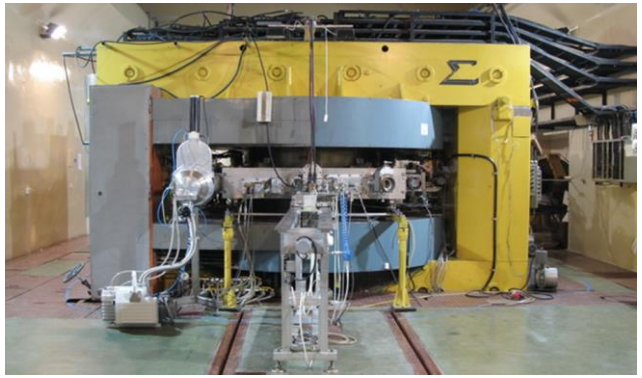
Fully functional research (with laboratories and experimental hall) and clinical proton therapy center

20 years of experience in 20 minutes

1. **Why the project in Kraków?**
2. **Key elements of the project**
3. **Building team**
4. **Patients and research**
5. **Lessons learned**

Why applications for proton therapy project at IFJ PAN Kraków were succesful?

1. **Human potential at IFJ PAN**
2. **Experience with cyclotrons**
3. Experience in fast neutron therapy
4. Eye proton therapy project
5. Good contacts between physics and medicine
6. Some local politicians helpful



- IFJ PAN - the biggest institute of Polish Academy of Sciences: 570 employees (220 Ph.D) + 90 PhD. Students
- High energy physics (CERN), nuclear physics, dosimetry labs, radiation physics, radiation biology
- Workshop: technicians and engineers
- Construction and exploitation of three cyclotrons – first cyclotron in Poland from 1955

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Experience in fast neutron radiotherapy with Centre of Oncology, at 12.5 MeV D U-120 cycltoron

Neutron radiotherapy unit
-radiotherapy unit developed at IFJ
- 5.6 MeV neutrons, horizontal beam only

Patients
- 486 patients (1978 – 1995)
- advanced head & neck cancer
- non-operable recurrences after mastectomy

Lessons learned:
- work with patiants
- building radiobiology and dosimetry teams

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Between 2011 – 2026 126 eye cancer patients from Krakow Universty Hospitals (Prof. B. Romanowska-Dixon) were treated

Eye treatment room at 60 MeV cyclotron developed at IFJ PAN 2001 -2011

Support from IAEA (S. Vatnistky)
- dosimetry
- training of two medical physicists at HMI Berlin and Clatterbrigde

Building up team and competences:
- dosimetry and QA
- therapy planning

2006 -2011: from 6 to 17 physicists

2. Key elements of the project

Key elements of the project (1)

- **Scientific environment**
- Location
- Funds
- Tender specification
- Construction
- Acceptance tests
- Commissioning

The National Consortium of Hadron Radiotherapy

Founded September 2006, 14 members

Kraków: IFJ PAN, AGH University, Jagiellonian University, Center of Oncology, Collegium Medicum UJ

Warsaw: Center of Oncology, Medical University, National Center of Nuclear Research, Warsaw Polytechnic, Warsaw University

Kielce: Holycross Center of Oncology

Silesia: Center of Oncology, Gliwice, Silesia University

Poznań: Center of Oncology

The major role of the consortium to:

- share responsibilities
- get together clinic and research
- moderate critics and ambitions

2. Key elements of the project (2)

- Scientific environment
- **Location**
- Funds
- Tender specification
- Construction
- Acceptance tests
- Commissioning

Very good location of IFJ PAN

- Close access to A4 highway (2 km), airport (10 km), public transport
- In the vicinity of the oncology clinic with high patient number
- In a place with the very good access, public transport etc
- Close to universities and research institutes
- Own building plot at IFJ PAN with access to infrastructure

Location of the project is the major source of conflicts – in many countries it blocked investment

2. Key elements of the project (3)

- Scientific environment
- Location
- **Funds**
- Tender specification
- Construction
- Acceptance tests
- Commissioning

Poland joined European Union on May 1, 2004

In 2007 -2013 60 billions € used for reconstruction of infrastructure in form of Structural Funds

1.3 billion € for infrastructure in science and technology

Three successful applications of IFJ PAN:

- 30 M€ (1st part)
- 20 M€ (2nd phase)
- 15 M€ (3rd phase)

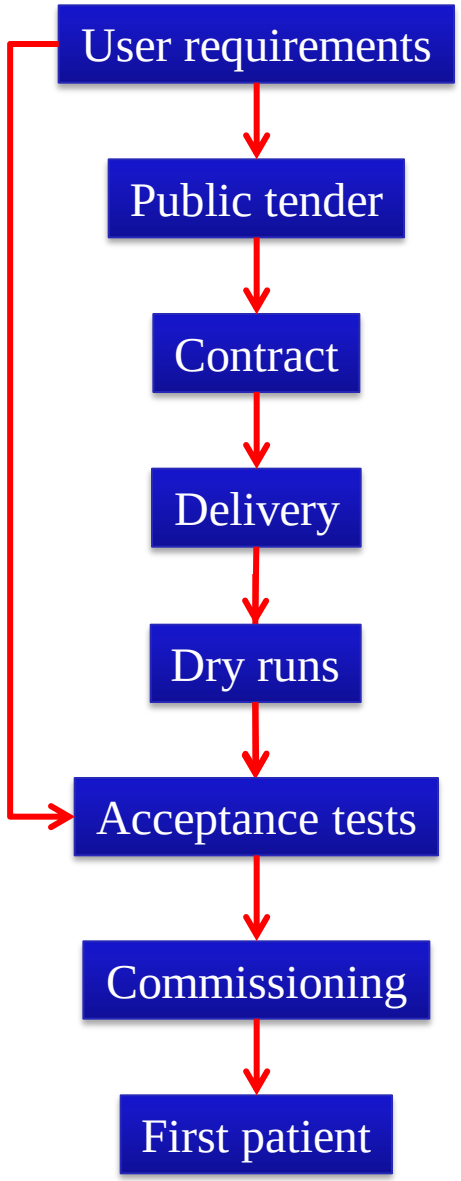
Cons:

complicated bureaucracy, unclear regulations,

audits, audits, audits

2. Key elements of the project (4)

- Scientific environment
- Location
- Funds
- **Tender specification**
- Construction
- Acceptance tests
- Commissioning



Challenges:
- Specification 4-5 years before starting the treatment
- Technology is changing fast
- Each new PT with somewhat different technology

Broad international consultations:
- Hakan Nystrom (Uppsala), Jonathan Farr (Essen), Alexandro Mazal (Orsay), Stanislav Vatnicki (IAEA) **Great help!**

Key decisions:
- technology: PBS + classical cyclotron
- possibility for facility to grow

Turn-key contract for system but…
- eye-treatment room – own construction
- individual contracts for TPS, CT, dosimetry etc (major savings!)
- careful specification for acceptance tests

2. Key elements of the project (5)

- Scientific environment
- Location
- Funds
- Tender specification
- Construction
- Acceptance tests
- **Commissioning**

CE marking is a legal requirement for medical devices intended for medical operation in Europe:

•The Medical Devices Directive (MDD) (Council Directive 93/42/EEC, revised as 2007/47/EC

Eye treatment room designed, built and integrated by IFJ PAN

- major savings (about 2 M€ as compared to about 8 M€)
- but getting the CE marking was a major undertaken: a few thousands of documents prepared

CE marking constitutes a major problem for self-developed facilities

3. Building team

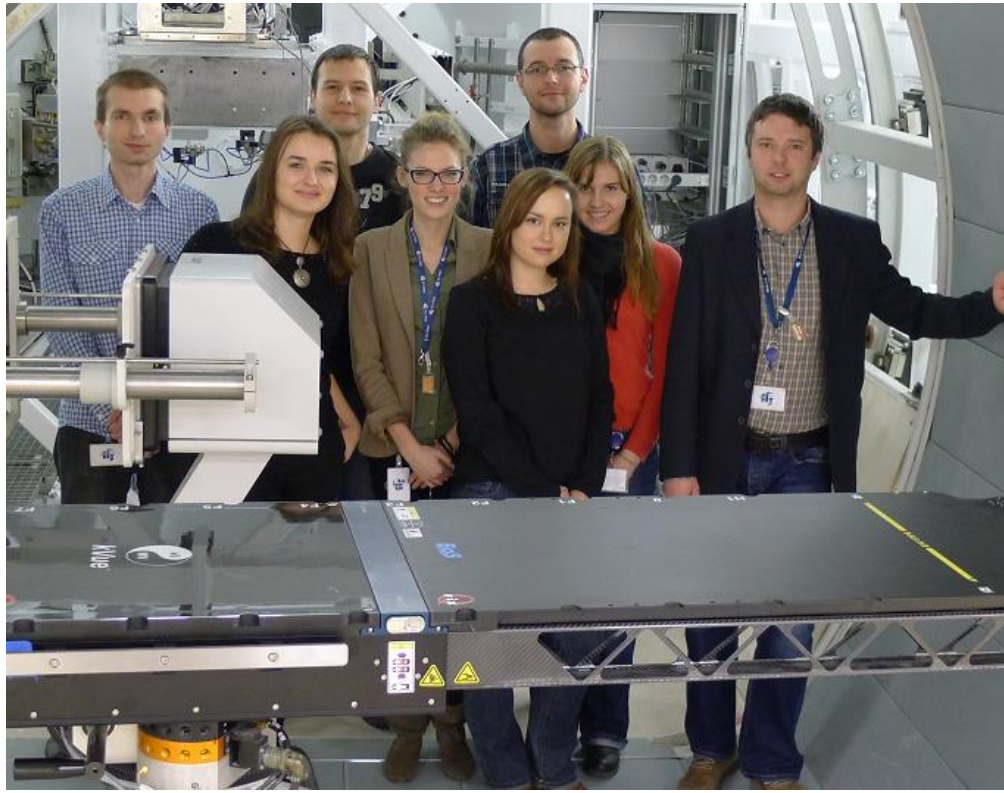
3. Building team (1)

- **Training by vendor**
- Ph.D. degrees in physics
- Specialization of medical physics
- International Collaboration

- We required training that will end-up with the IBA certificates for the operators, technicians and IT people
- **Operation and service is entirely in hands of CCB- IFJ technicians, engineers and I staff. IBA keeps one engineer at our site. It brings savings by the factor 3-4**
- Our technicians, radiation therapists, physicist and clinicians went to running PT centers for hands-on training
- In every tender we requested substantial training for personnel

3. Building team (2)

- Training by vendor
  - A lot of young physicists came to perform research and do Ph.D. degree
- **Ph.D. degrees in physics**
  - Their competences helped enormously in acceptance tests, preparation of procedures, QA, dosimetry and treatment planning
- Specialization of medical physics
  - 2/3 of them continue as a highly qualified medical physicist
- International Collaboration
  - In 8 years 12 Ph.D. degrees



3. Building team (3)

- Training by vendor
- Ph.D. degrees in physics
- **Specialization of medical physics**
- International Collaboration

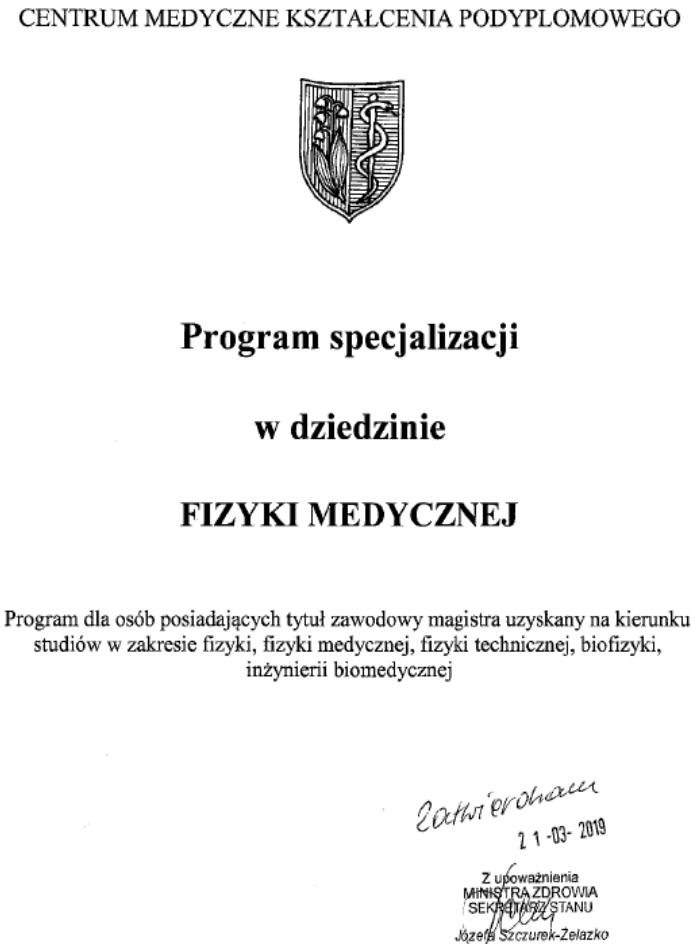
In Poland medical physicist only with specialization can work with patients

Specialization takes 3 years (6000 hours!) and requires internships in different clinics

The program is approved by Ministry of Health

It ends with a examination (written + oral) in front of the Commission appointed by Ministry of Health

At CCB 7 medical physicists made specialization – which was a major undertaken



CENTRUM MEDYCZNE KSZTAŁCENIA PODYPLOMOWEGO

Program specjalizacji

w dziedzinie

FIZYKI MEDYCZNEJ

Program dla osób posiadających tytuł zawodowy magistra uzyskany na kierunku studiów w zakresie fizyki, fizyki medycznej, fizyki technicznej, biofizyki, inżynierii biomedycznej

Zatwierdzono
21-03-2019
Z upoważnienia
MINISTRA ZDROWIA
SEKRETARZ STANU
Józefa Szczurek-Zelazko

3. Building team – how many staff we need?

Proteus C-235
(10 persons)

IT
(3 persons)

Eye treatment
(4 persons)

Dosimetry and QA
(8 persons)

Therapy Planning
(9 persons)

Radiation therapetists
(12 persons)

Quality Control
(2 persons)

Secretaries
(2 persons)

Total Staff: 50 persons + administration of IFJ + services of IFJ

4. Patient treatment and research

4. Patient treatment and research organization

1. CCB –IFJ PAN is not a medical institution – it was founded from the project supervised by Ministry of Science

2. We have contracts with National Institute of Oncology and University Hospitals – they rent the medical area.

3. Our staff is responsible for operation of facility, handling patients by radiation therapeutists, dosimetry, QA, partly for the treatment planning

Adults , Children

National Institute of Oncology
5.5 km from IFJ PAN

Eyes

University Hospital
7 km from IFJ PAN

Proton therapy facility

CCB- IFJ PAN

4. Patient treatment and research

indications financed by the National Health Funds in Poland (2016-2023)

- rare tumors
- not all potential patients from Poland directed to CCB (trust? competition??
- reimbursement does not follow inflation
- private patients not allowed
- difficult financial situation

ICD-10	Tumors (anatomical localization & histology)		Patients
C41	the base of the skull, next to spinal cord	chordoma, chondrosarcoma	adults & children
C49	periveral area	soft tissue and bone sarcomas	children
C30	paranasal sinuses	malignant melanoma, neuroblastoma, adenocystic carcinoma, mucoepidermoid carcinoma, undifferentiated carcinoma	children
C31	irradiaton of the cerebrospinal axis	medulloblastoma, pineal germ cell tumor, malignant ependymoma, choroid plexus carcinoma	children
C71	Gliomas	WHO G1, G2	adults
	Hodgkin disease		adults

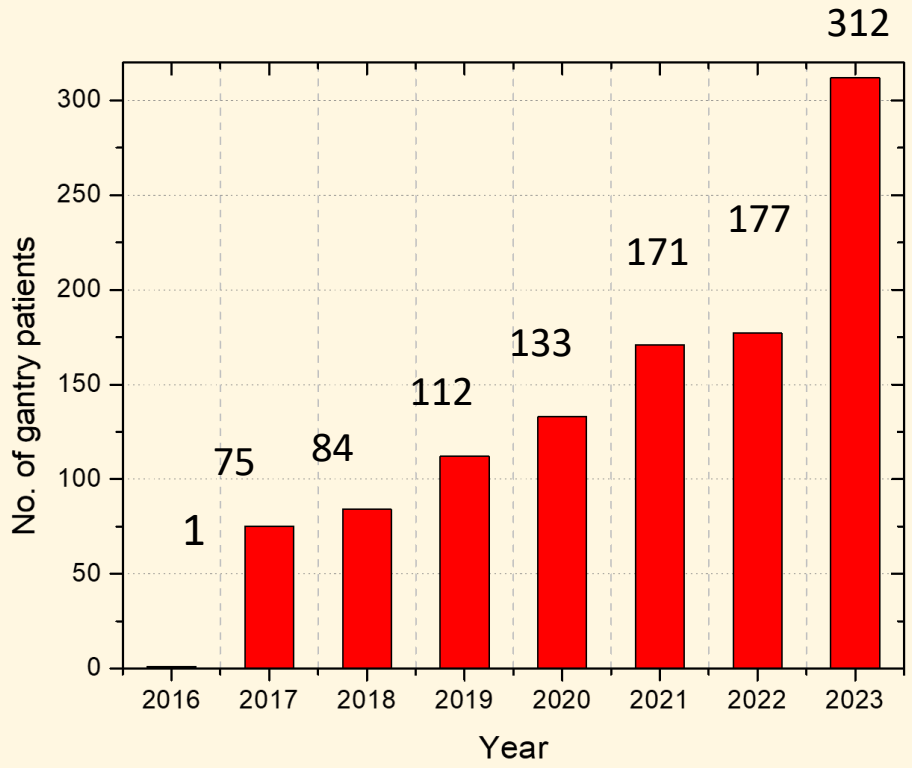
4. Patient treatment and research

Patient statistics

Proton eye melanoma (2011- 2023):
363 patients (128 on previous AIC-144 cyclotron);

Gantry pencil scanning beam (2016 - 2023):
1108 pacjentów including 100 children

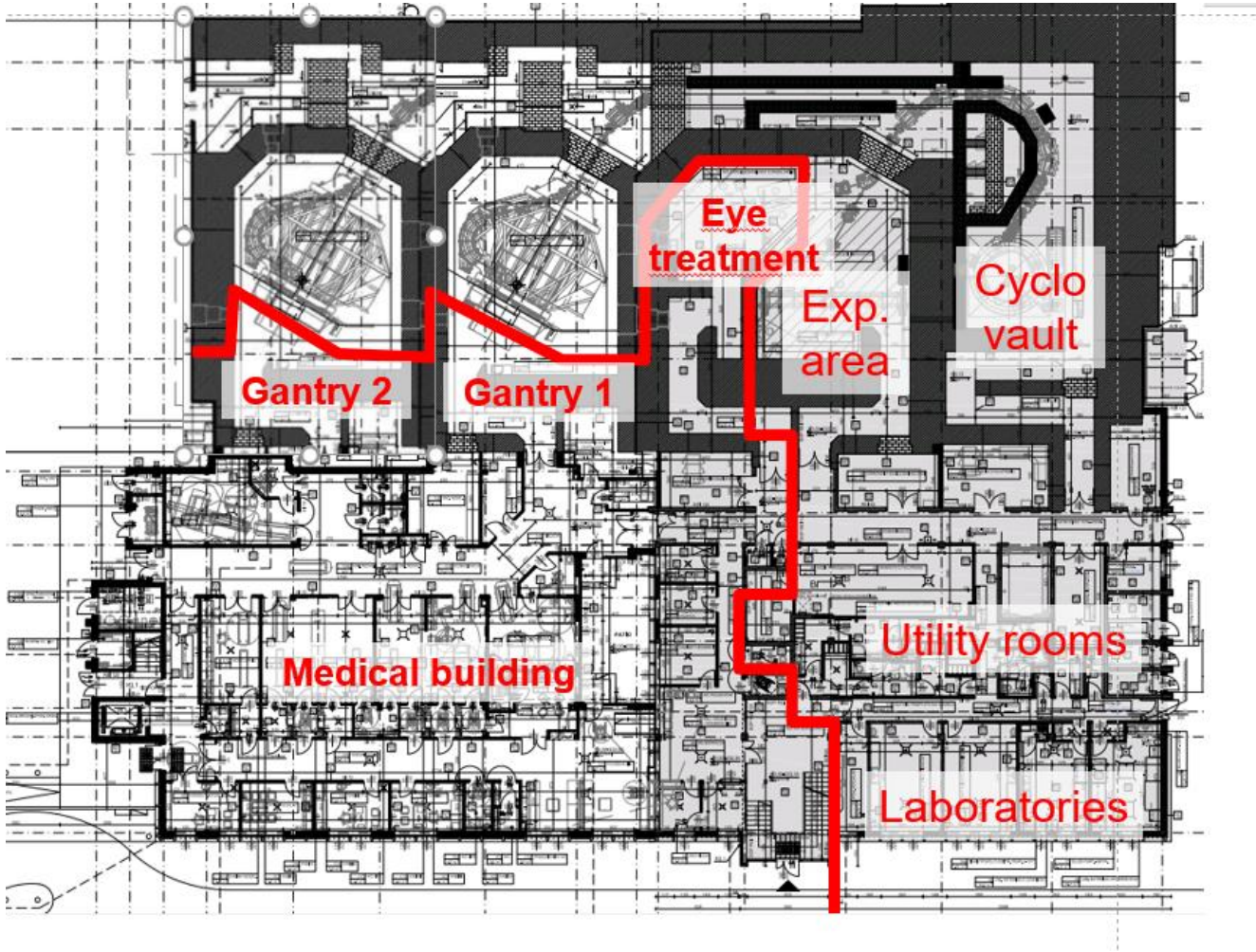
Until 08.2024 completed treatment more than 1550 patients



Number of patients (yearly)

4. Patient treatment and research

- **CCB was funded as a research user facility**
- Medical and experimental area are separated
- The experimental area is used mainly by nuclear physics users
- The three medical lines (2 gantries + eye line) are used for medical physics, detector experiments and radiobiology
- There are two dedicated radiobiological laboratories and rooms for preparation of experiments in physics
- International Advisory Committee approves the plans of experiments
- ENSAR, INSPIRE – EU funded TNA projects
- till 2024: 35 institutions from 16 countries, about 250 scientists



The main reaserch topics related to proton therapy – CCB IFJ PAN

Clinical:
- protons vs. photons
- hipofractionation
- indications
- ……..

Accelerators:
cheaper, simpler, less energy consumption, less service

Radiobiology:
- RBE = 1.1 ???
- Treatment Planning Systems with variable RBE
- …..

Beam Delivery
- superconducting gantries
- grid therapy
- 3D printed compensators

Patient positioning:
- adaptive PT
- range monitoring
- proton radiography

Dosimetry
- LET dosimetry
- 2D, 3D dosimetry
- unwated doses from scattered radiation

About 100 papers published

Lessons learned from the CCB project - summary

1. **It is important that the project is located in a stable institution with sufficient resources, which could be used in case of problems/crises.**

2. **Experience of the institution in handling the big projects is essential**

3. **Presence of experts in operation of accelerators, in radiation physics, radiation protection, detectors, radiobiology - very useful.**

4. **Collaboration with all partners around – ”win win” situation needed to select the centre location**

5. **Training at different levels- by research, by specialization, by collaboration, by internships in other centers**

6. **Leadership of a physician (radiation oncologist) with strong personality and position crucial for the success of the project . However, the most work will be done by the project leader (physicist)**

7. **Difficult task: selection of the technology – the centre will start in 5-10 years.**

8. **”Do it yourself” or ”buy” – the big problem of the Medical CE certificate. Buy when only possible.**

9. **Work early on the financing of therapy - indications, patient flow, in agreement with conventional therapy.**

10. **Involve physicians and physicists from many centers and help in their carriers (projects, internships, common patient data etc.)**