EIB Support to Investments in Proton Therapy: Key Issues and Proposed Action

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Felicitas Riedl

General features to be fulfilled by all Bank-financed health projects

- The investment must be **in line with EU and international agencies' sector policies and established good practice**; and the corresponding national, regional and local policies and strategies;

- **Technologies and service models** supported by Bank investments are based on **sound scientific evidence** demonstrating their **effectiveness and efficiency**;

- Projects must strive to **deliver high quality and affordable health care to the general population**, and support **equity of access**; and it must be possible to measure the output generated by the investment and to establish accountability;

- The investment must be **economically viable**, and foster sustainable long-term growth and population well-being.

The technology: Radiation therapy for cancer treatment

Photon therapy: Standard radiation therapy for most cancers

- Linear accelerator
- Gamma knife / cyber knife

Charged particle (hadron) therapy:

- **Proton**
- Neutron
- Heavy Ion

- Sophisticated, but much more costly than photon therapy
- Insufficient or incomplete evidence for better results (efficacy) compared with photon therapy for most applications

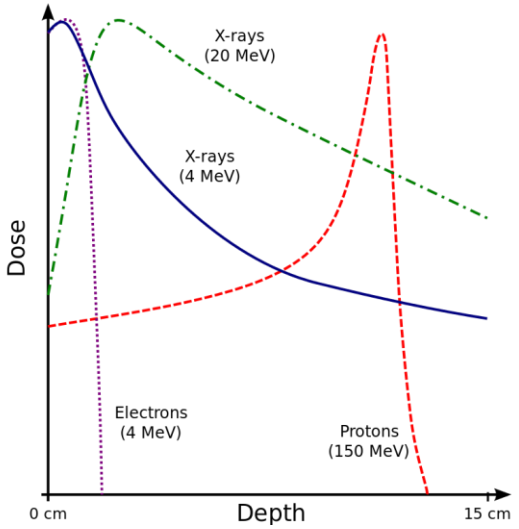
Proton Therapy Basic Features

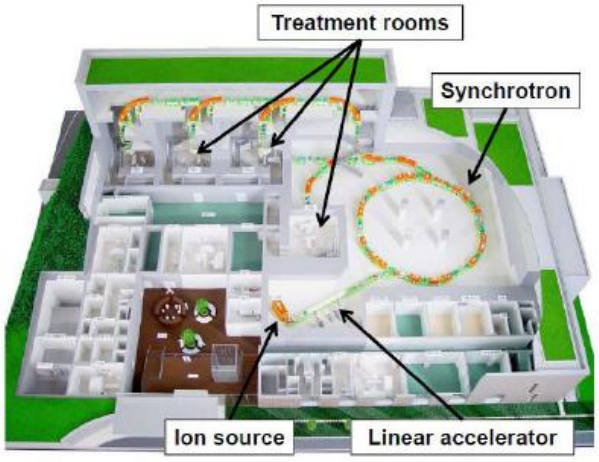
- **Particle therapy** treatment techniques (*also called **hadron therapy***) are based on the utilization of Neutrons, Positive Ions and Protons.

- **Proton therapy** is a type of non-invasive radiation which uses charged particles instead of X rays to **more precisely deposit radiation dose** as compared with traditional external beam radiotherapy.

- The energy deposited at a given depth is inversely proportional to the square of the velocity of the particle. This release of energy (or dense ionization) is called a **Bragg peak**.

- The fixed-energy proton beam, accelerated through a cyclotron (or **synchrotron**), is distributed by the high energy beam transport line to the treatment rooms.





Challenges of particle therapy treatment centres

- **Current indication for proton therapy for only a small number of cancers**
  - Some skull, spine, ocular soft-tissue cancers
  - Cancers in children (long-term side effects of radiation)

- **Treatment very costly and time consuming**
  - High unit costs per treatment episode
  - Lack of established reimbursement scheme from public payers (often case by case decision)
  - Poor financial track record of (commercial) operators
  - Over-optimistic business plans, revenue forecast not met

- **Geographic coverage**
  - Small countries may have too few patients to justify own centres
  - Access for patients from other regions / countries
  - Knowledge about technology and treatment opportunities and guidelines
  - Referral system unclear

- **Limited research activity (especially for rare cancers)**
  - Lack of sufficiently large patient cohorts
  - Resource limitations in financially constrained public systems
  - Few facilities with explicit research focus and programme

- Obstacles for project implementation and operation
  - Delays in investment project implementation and start-up of operation
  - Human resources constraints

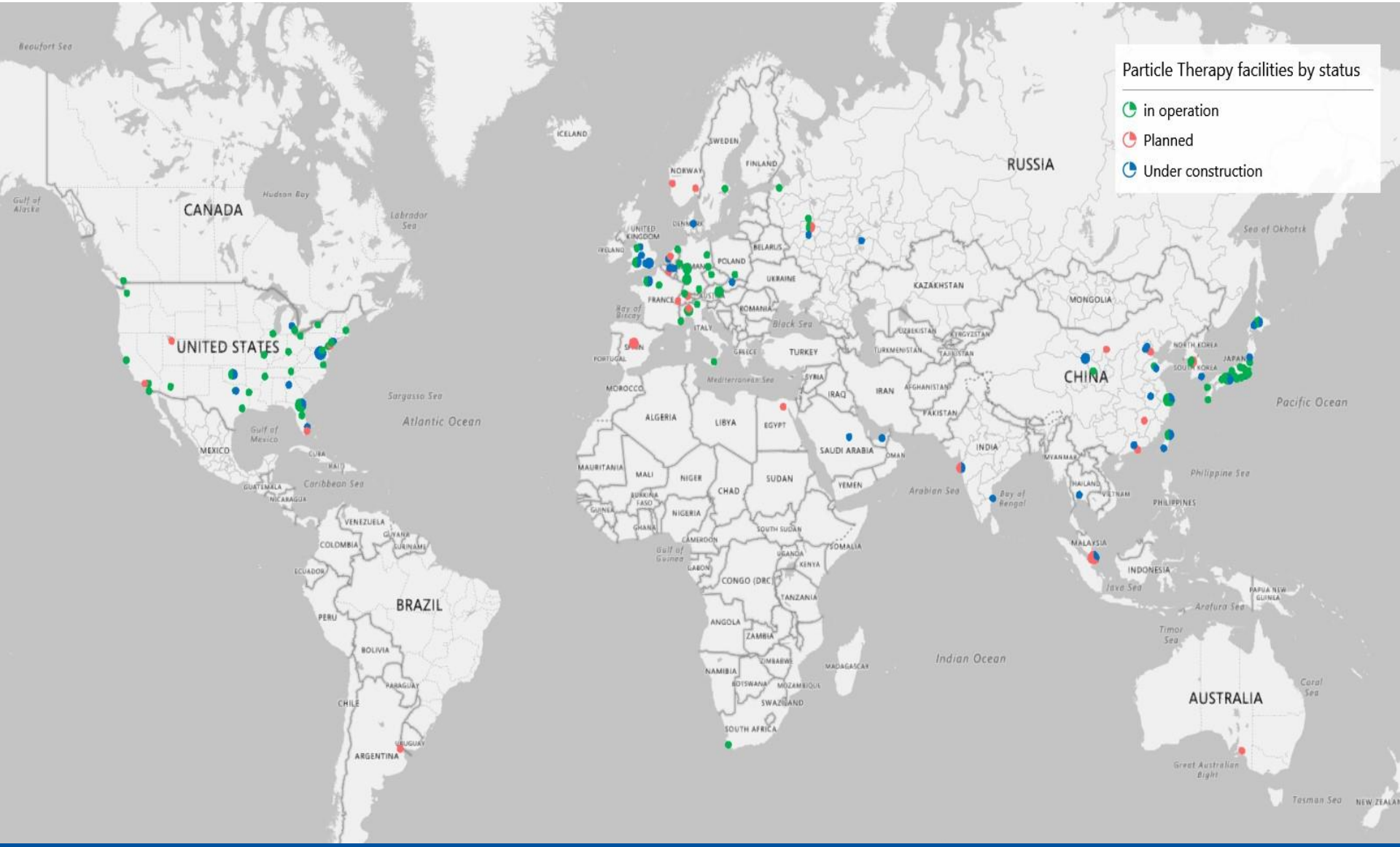
External factors impacting on treatment results

Various external factors seem to affect the actual output of a Centre and treatment outcomes:

- Formal approval of indications and reimbursement tariffs at central level; regulatory process
- Patient selection, referral and decision chain (inter-regional or international; curative vs. palliative)
- Quality of surgery prior to particle-therapy treatment
- Logistics (patient travelling and accommodation arrangements and costs coverage)
- Case mix (different time and productivity capacity)
- Training and recruitment of specialist (medical and technical)
- Competing technologies (including pharma) and further developments of photon therapy (IMRT or robotic)
- Project Management capacity for the planning, design, construction and installation phases, including procurement
- Operations and maintenance costs
- Pressure on media and marketing by private players beyond approved indications

European Investment Bank The EU bank

The Particle Therapy World



…and the European landscape

Particle Therapy Centres in Europe

- **20** Centres in operation

Austria	1
Czech Republic	1
France	3
Germany	6
Italy	3
Netherlands	1
Poland	1
Sweden	1
Switzerland	1
United Kingdom	2

- **11** Centres under construction

Belgium	1
Denmark	1
France	1
Netherlands	2
Slovak Rep	1
United Kingdom	5

- 7 Centres planned…….

  ……but several more in the pipeline

Belgium	1
Italy	1
Netherlands	1
Norway	2
Switzerland	2

Current issues and questions for EIB

Shall the EIB expand lending to proton therapy treatment centres?

- Support to strategic investments that promote the use of innovative technologies
- Facilitate the roll-out and improvement of technology and procedures
- Long-term lending for infrastructure with a relatively long economic life

Trends observed:

- Single-room centres seem to have operational and financial advantages over multi-room centres
- Investment costs have seen a substantial reduction in the last 2-3 years
- Clinical results in some areas are promising
- Public payers / social health insurance reimbursement schemes increasing

Current point of view: Lending can possibly be justified if

- Public sector is involved
- Authorisation and permits are clear and available
- Tariffs specified and cost-covering
- Appropriate technology and size of centre
- Business plan financially sustainable

- ***Remains a case-by-case assessment***
- ***General policy still evolving and to be adapted and approved by management***

Opportunities and challenges: The case for a European approach

- **Kick-start strategic investments**:
  - Experience from technology development in the past suggests a potential for accelerated deployment of new technologies with a joint initiative
  - Exploration of economies of scale and scope
  - Improve patient access to treatment
  - Engage (European) industry to foster innovation and R&D
- **Informed planning** to guide efficient allocation of (public) investments in infrastructure
- Prepare for **future growing demand** due to demography
- Follow-up on basis laid by European research networks and international agencies

Sub-group objectives**: Cooperation for **information exchange** and **avoiding duplication of efforts

Study: Part A – Mapping and Fact Finding

- What are the current **evidence-based indications** for using proton therapy (mapping of the current state of play - which therapy for which indication including on-going research activities)? What are the indications where clinical studies are ongoing?

- What are the different **features** and the **pros and cons** of currently available **proton therapy systems** in terms of clinical value?

- What are the **potential future indications** for using proton therapy?

- What **human resources** need to be available for running a proton therapy facility and what skills are needed?

- What should be **research priorities** for identifying further indications of using proton therapy?

Study: Part B – Additional Analysis

- **Cost-effectiveness**:
  - different features and pros and cons of currently available systems
  - Catchment area: characteristics of a cost-effective catchment area for facilities?
- **Reimbursement schemes:**
  - Use of existing cross-border reimbursement schemes?
  - What are the ideal characteristics of such a scheme, ensuring both cost covering operation of centres and equitable and fair access of all potential patients in the catchment area?
- **Geography**: Best distribution in the geographical area of participating countries regardless of borders?

⇒ Report will be a technical document that may facilitate relevant analysis by the EIB and the Member States.

⇒ It will not provide political recommendations on national competences such as access or reimbursement of healthcare services.

Study: Timeframe

- Review and update clinical evidence on indication for particle therapy: end 2018
- Mapping and market study: First half 2019
- Discussion and next steps – action plan: late Spring 2019
- Contacts with Member States' Institutions desired