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

Sub Group on Proton Therapy
Steering Group on Health Promotion, Disease Prevention and Management of Non-communicable Diseases

Luxembourg, 22 October 2018

The EIB Group: Who are we?

Provides finance and expertise for sound and sustainable investment projects

Leading developer of risk financing for innovative SMEs

Investments in Proton Therapy Research and Treatment Infrastructure

Background

- Growing number of financing requests for high-end proton therapy treatment centres
- Public and private promoters
- Private, commercial operators' requests increasing
- Large scale, resource-intensive investments
  - Expensive equipment and buildings
  - Highly specialized human resources
- Past lending only for projects with research component
- **Update of EIB Appraisal Guidelines and eligibility criteria**

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.

Challenges for investment appraisal 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
  - Poor financial track record of commercial operators
  - Delays and obstacles in project implementation
  - Lack of established reimbursement scheme from public payers (often case by case decision)
- 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

Challenges for project implementation of proton therapy treatment centres

- **Implementation delays** and problems with technology specifications and accreditation/ certification
- **Patient numbers and workload over-optimistic**: Most centres only treat 100-200 patients during first few years
  - Need for adjustment in treatment protocols
  - Deficits in market assessment
  - Lack of public support
  - Referral and access
- **Unclear tariffs and reimbursement schemes**
  - High unit costs per treatment episode
  - Lengthy negotiations with insurers / payers
  - Legal action ongoing in some cases
  - Number of licenses in some countries reduced under insurance pressure
  - Fixed tariffs only for a very limited number of indications
- **Business plan and revenue forecast not met**
  - Centres run into financial difficulties
  - Distressed centres switch to treating commercial, out-of-pocket patients (e.g. prostate)
  - Research neglected
- **Human resources constraints**
  - Lack of qualified personnel
  - Technical support services

The technology: Radiation therapy for cancer treatment

Photon therapy: Standard radiation therapy for most cancers

- Linear accelerator
- Gamma knife / cyber knife

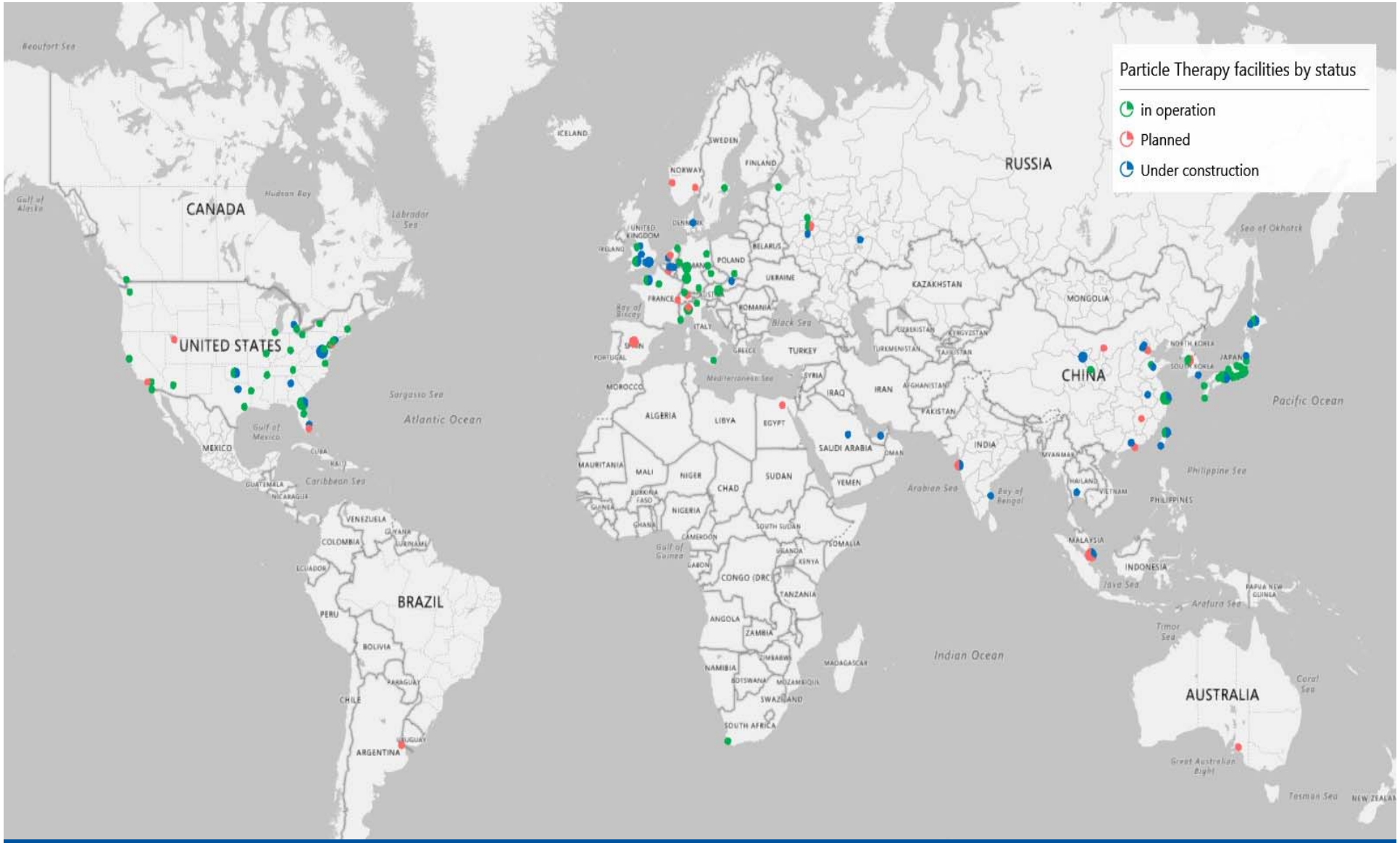
Charged particle (hadron) therapy

- **Proton**
- Neutron
- Heavy Ion

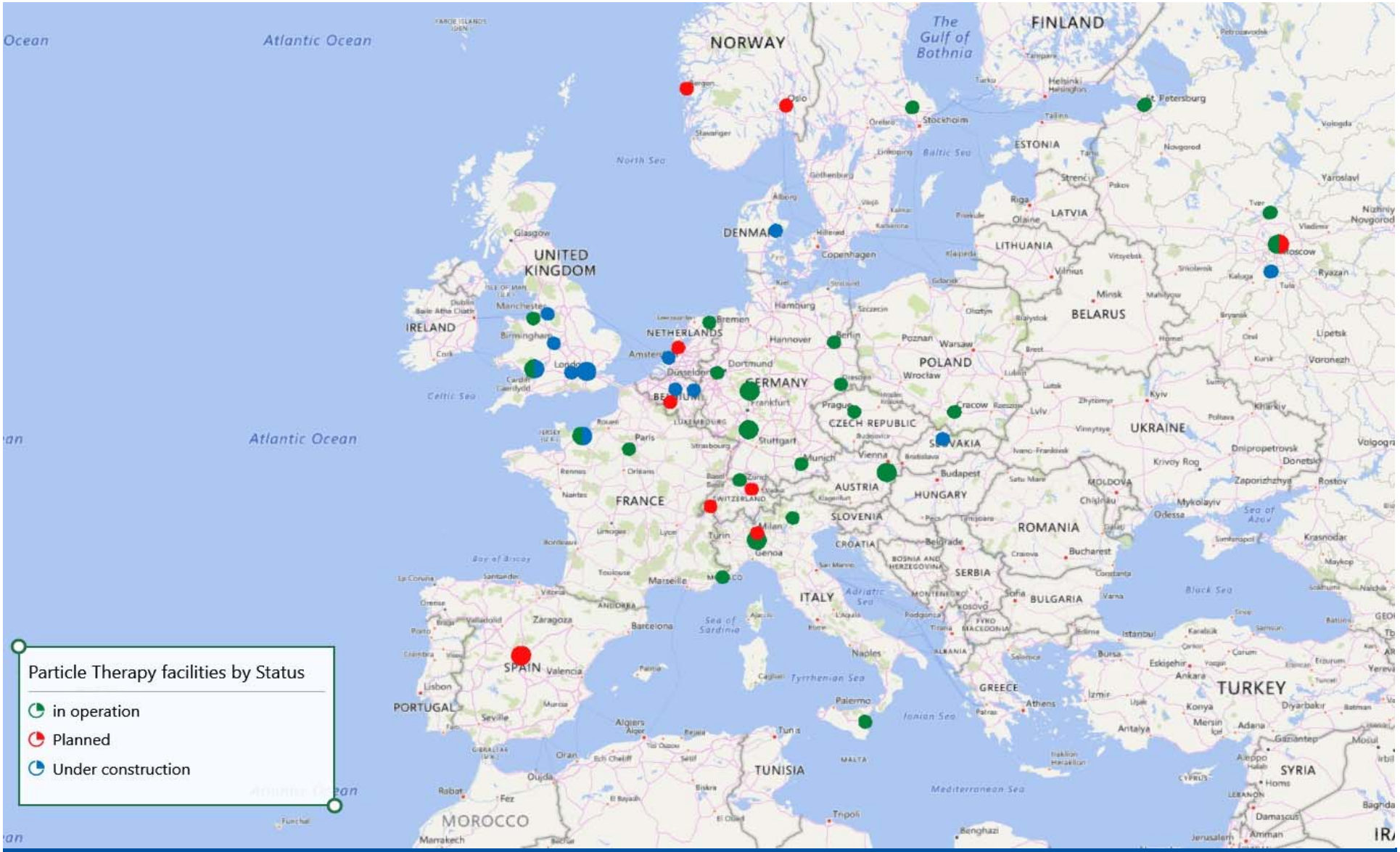
Common features

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

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

Operational Particle Therapy Centres

COUNTRY	CITY	WHO	PARTICLE	BEAM DIRECTIONS	START of TREATMENT
Austria	Wiener Neustadt	MedAustron	p	2 fixed beams**, 1 gantry** (under construction)	2017
Austria	Wiener Neustadt	MedAustron	C-ion	2 fixed beams**	2017
Czech Republic	Prague	PTC Czech r.s.o.	p	3 gantries**, 1 fixed beam	2012
France	Caen	CYCLHAD	p	1 gantry**	2018
France	Nice	CAL/IMPT	p	1 fixed beam, 1 gantry	1991, 2016
France	Orsay	CPO	p	1 gantry**, 2 fixed beams	1991, 2014
Germany	Berlin	HZB	p	1 fixed beam	1998
Germany	Dresden	UPTD	p	1 gantry***	2014
Germany	Essen	WPE	p	4 gantries***, 1 fixed beam	2013
Germany	Heidelberg	HIT	p	2 fixed beams, 1 gantry**	2009, 2012
Germany	Heidelberg	HIT	C-ion	2 fixed beams, 1 gantry**	2009, 2012
Germany	Marburg	MIT	p	3 horiz., 1 45deg. fixed beams**	2015
Germany	Marburg	MIT	C-ion	3 horiz., 1 45deg. fixed beams**	2015
Germany	Munich	RPTC	p	4 gantries**, 1 fixed beam	2009
Italy	Catania	INFN-LNS	p	1 fixe beam	2002
Italy	Pavia	CNAO	p	3 horiz., 1 vertical, fixed beams	2011
Italy	Pavia	CNAO	C-ion	3 horiz., 1 vertical, fixed beams	2012
Italy	Trento	APSS	p	2 gantries**, 1 fixed beams	2014
Netherlands	Groningen	UMC PTC	p	2 gantries***	2018
Poland	Krakow	IFJ PAN	p	1 fixed beam, 2 gantries	2011, 2016
Sweden	Uppsala	The Skandion Clinic	p	2 gantries**	2015
Switzerland	Villigen	CPT	p	3 gantries**, 1 fixed beam	1984, 1996, 2013, 2018
United Kingdom	Newport	Proton Partner's Rutherford CC	p	1 gantry**	2018
United Kingdom	Clatterbridge		p	1 fixed beam	1989

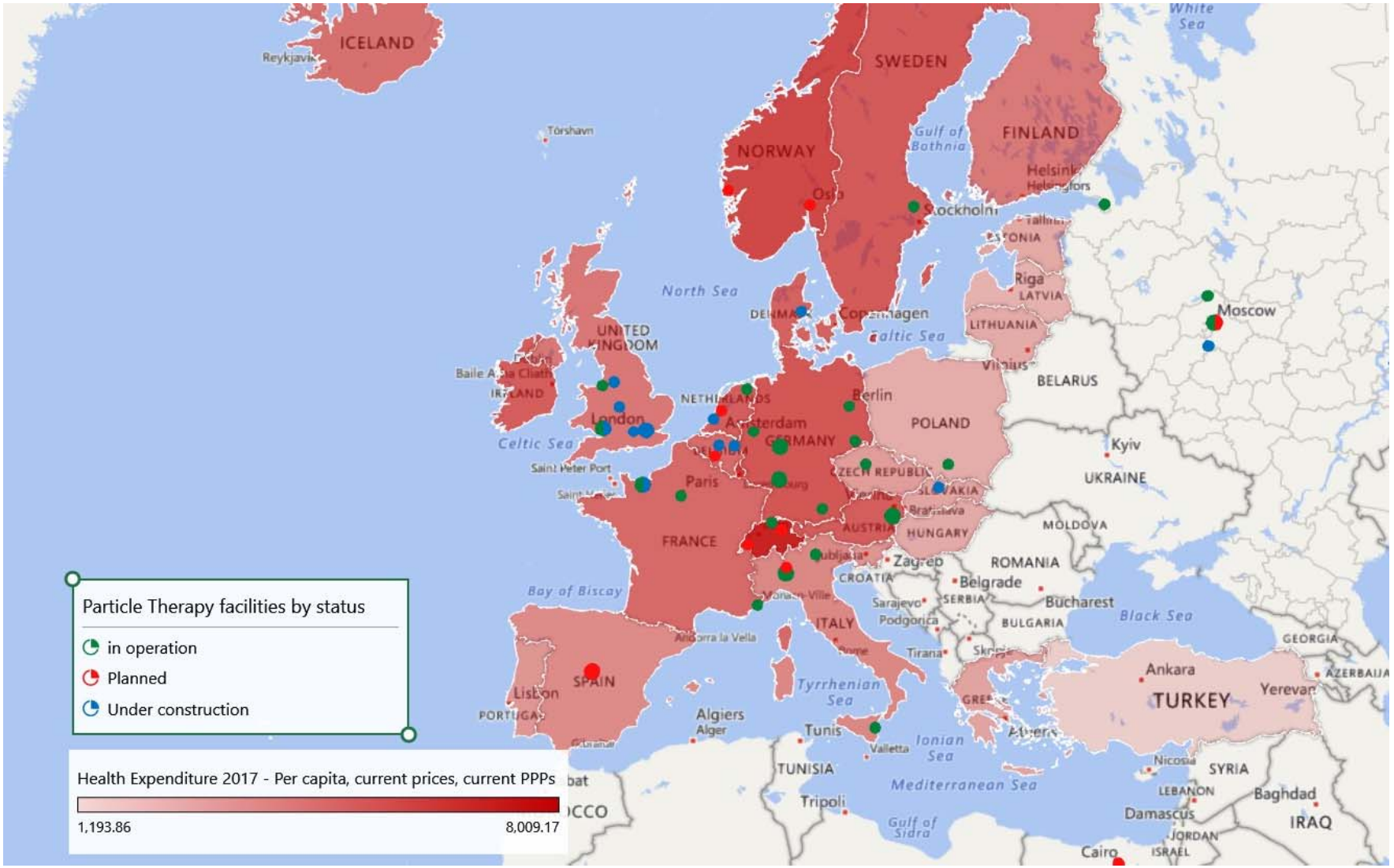
Particle Therapy Centres under construction

COUNTRY	CITY	WHO	STATUS	PARTICLE	BEAM DIRECTIONS	Treatment Rooms	START of TREATMENT PLANNED
Belgium	Louvain	ParTICLe	Under construction	p	1 gantry (PBS),	2	2019
Denmark	Aarhus	DCPT	Under construction	p	3 gantries,	4	2018
France	Caen	ARCHADE	Under construction	C-ion	1 fixed beam (r&d)	1	2023
Netherlands	Delft	HollandPTC	Under construction	p	2 gantries,	3	2018
Netherlands	Maastricht	ZON PTC	Under construction	p	1 gantry	1	2018
Slovak Rep	Ruzomberok	CMHPTC	Under construction	p	1 horiz. fixed beam	1	?
United Kingdom	London	Proton Partners Int.	Under construction	p	1 gantry	1	2019
United Kingdom	London	PTC UCLH	Under construction	p	3 gantries	3	2019
United Kingdom	Manchester	The Christie Proton Therapy Center	Under construction	p	3 gantries	3	2018
United Kingdom	Newport, UK	Proton Partners Int.	Under construction	p	1 gantry	1	2018
United Kingdom	Reading, UK	Proton Partners Int.	Under construction	p	1 gantry	1	2018

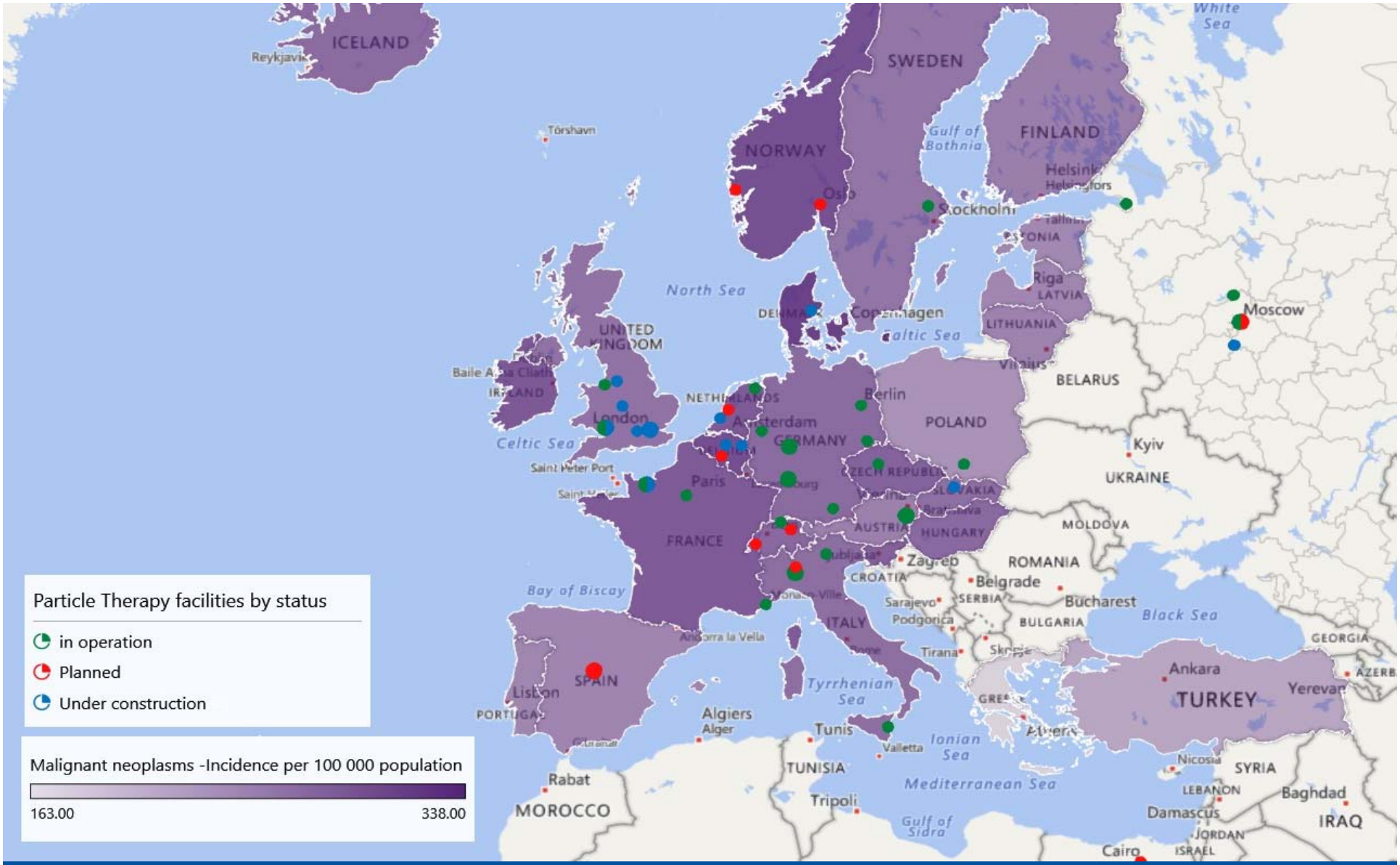
Particle Therapy Centres planned

COUNTRY	CITY	WHO	PARTICLE	BEAM DIRECTIONS	Treatment Rooms	START PLANNED
Belgium	Charleroi	University Hospitals Wallonia	p	1 gantry	1	2020
Italy	Milan	European Institute of Oncology	p	1 gantry	1	2020
Netherlands	Amsterdam	APTC Amsterdam	p	2 gantries	2	2021?
Norway	Bergen	Haukeland University Hospital	p	1 gantry	1 (2)	2023-2025
Norway	Oslo	Norwegian Radium Hospital	p	3 gantries,	3	2023
Switzerland	Galgenen	PTC Zürichobersee	p	4 gantries	4	2020
Switzerland	Lausanne	CHUV	p	1 gantry	1	2020

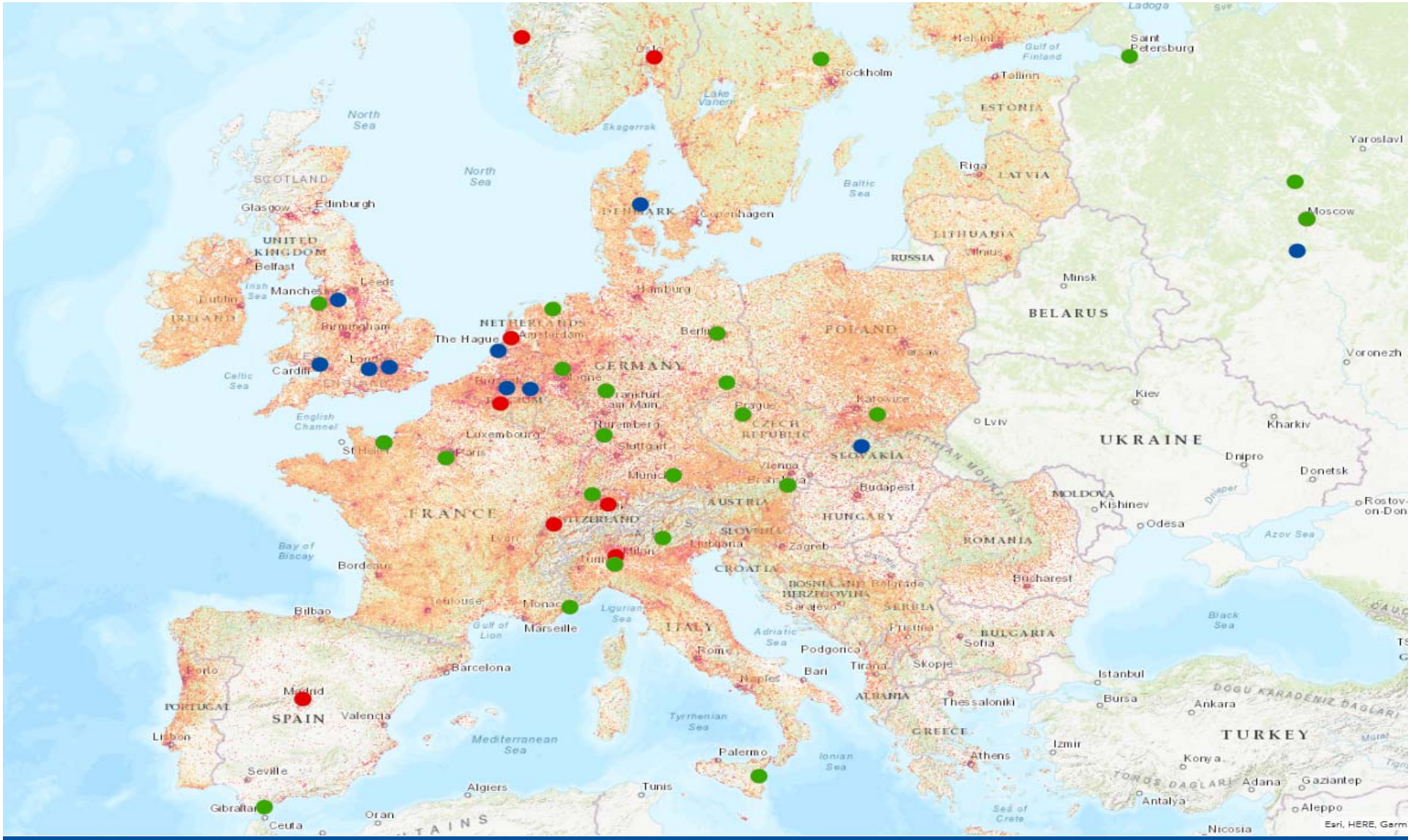
Health expenditure per capita



Cancer incidence



Population density



Particle Therapy Centres
Treatment Capacity Estimates

		Number of patients per year		
	No. Centres	400	600	800
Existing	20	8,000	12,000	16,000
Construction	11	4,400	6,600	8,800
Total		***12,400***	***18,600***	***24,800***
Planned	7	2,800	4,200	5,600
Total		***15,200***	***22,800***	***30,400***

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

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 possible be justified if

- Public sector is involved
- Authorization 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***

Priority questions

- Capacity needs for EU?
- Actual tariffs and public coverage?
- Referral system to ensure equity of access and cross-border cooperation?
- Best technology?

Priority questions

- Project management good practice:
  - **Planning** – construction design, permits, functional set-up of centres
  - **Implementation** - regulatory framework, technical expertise during construction
  - **Operation** – treatment planning time, patient logistics, nuclear safety, business plan and financial sustainability, human resources

Mapping Report

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

Mapping Report: current availability and use of proton therapy centres across the EU – resources and stakeholders

- **Proton therapy treatment**: **Indications and provision**
  - Efficacy of proton therapy compared with alternative treatment options;
  - Good practice: standard treatment guidelines and clinical protocols,
  - Clinical evidence and studies' results
  - Current access in public and private sectors
  - Integrated care structures
  - Member States' referral systems including equity of access,

- Overview of **technology,** manufacturers of proton therapy equipment and systems

- **Human resources**
  - Staffing and skills requirements
  - Training programmes

Mapping Report (2)

- **Financial and economic evidence:**
  - Cost- effectiveness compared with alternative treatment options
  - Investment costs
  - Operating costs

- **Regulatory aspects:**
  - Member States' licensing and accreditation requirements,
  - Supervision of treatment quality and service delivery,
  - Safety / radiation protection

- **Research and training programmes**:
  - Research results and data access,
  - Training and education programmes for staff.

- **Case studies** and experience from existing centres

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?

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

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

Discussion

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