





Clinical relevance and costeffectiveness of proton therapy 2018 : situation in France and perspectives

French Ministry of Solidarities & Health

Directorate General for Health



3 centres in operation (France 2018)



Orsay Proton Therapy Center, Institut Curie 1991: First eye treatment; 1993: First intracranial treatment; 2006: First paediatric treatment < 6 yo, under anesthesia. 235 MeV cyclotron equipment. 3 treatment rooms including one pencil beam scanning on isocentric arm. Capacity = 600 patients of which 80 children / year



ORSAY

YON

Italy

Germany

North Africa

South Africa

NICE

CAEN



2 treatment rooms including one 4D scanner

- Proteus[®]One, recent high energy 235 MeV proton therapy equipment, commissioned in June 2016
- Medicyc, low energy 65 MeV proton therapy system, for the treatment of eye tumors, commissioned in June 1991.

Capacity = **250 patients of which 50 children / year** Convention signed with the Lyon Léon Bérard Center

- 3. Normandy Center of Proton Therapy, Caen François Baclesse / CYCLHAD center. Opened July 5th, 2018. Total estimated costs: € 76,5 millions (Philippe Lagalle CEO)
 - Proteus[®]One, recent high energy 235 MeV proton therapy equipment

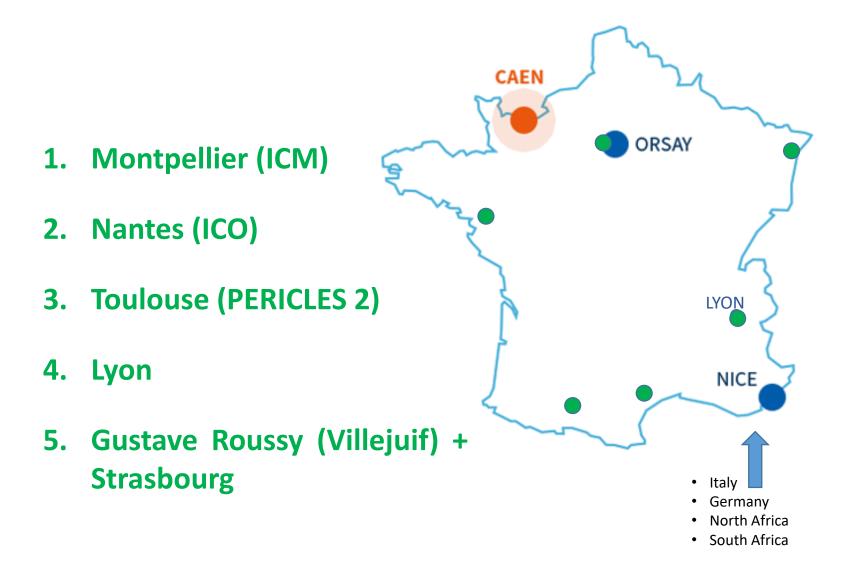
Capacity = 340 patients of which 90 children / year

2022 : Cyclotron Cyclone 400 carbon ion accelerator expected for **carbon therapy** (cost 55 millions € - World premiere)



Additional centers (2020-2025)?

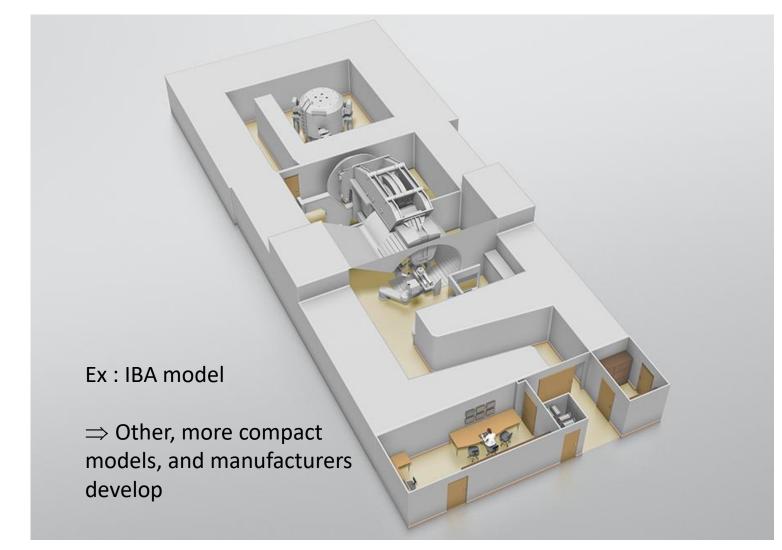






3D model of ProteusOne





- Total 50 to 70 millions € investment of which 37 millions € for equipment
- Estimated annual operating costs : 9 millions € / year



Principal indications / treated populations in France



- **384 000 patients** newly diagnosed with cancer each year in France
- Since 1991, a total of 14 000 patients treated with proton therapy (PT) in France
- **PT reimbursed indications :** Primitive tumors of the eye (intraocular melanoma), paediatric tumors, chordomas and chondrosarcomas of the skull and spine base
- ADULT INDICATIONS

Consensus: Primitive tumors of the eye (intraocular melanoma), chordomas and chondrosarcomas of the skull and spine base

More evidence needed :

Priority : sarcomas, other tumors of the nervous system, head and neck tumors, Hodgkin lymphomas

No priority : lung cancers, gynecological and breast cancers, prostate cancer and gastrointestinal tumors.

CHILDREN INDICATIONS

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Consensus / priority : 1. Brain tumors (except palliative or poor prognosis situations) which are the more frequent radiation candidates in childhood
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- 2. Sarcomas (including Ewing tumors, osteosarcomas, para meningeal rhabdomyosarcomas ...
- 3. Eyes tumors
- 4. Neuroblatomas

Report of the French National Cancer Institute (INCa) : Protonthérapie, indications et capacité de traitement - Juin 2016 - ISBN : 978-2-37219-220-0 ; ISBN net : 978-2-37219-221-7





- **2015** : **In Orsay:** 995 sessions. 600 patients, of which 78 children. 395 for eye tumours. % of children increases gradually for the last 5 years. 32% of children were under general anaesthesia
- **1** Proton Therapy center for **22** million inhabitants / 1 treatment line for **11** million inhabitants
- Reference publications^{1, 2}: 10-15 % of irradiated ADULT patients should be treated with proton therapy. In France, 205 000 patients treated via radiotherapy in 2015. This would correspond to 20 000 to 30 000 adult patients/year.
- Experts estimate at 410 the number of children and young adults per year that are eligible for a proton therapy for intracranial tumors and a maximum of 100 to 150 for extra-cranial locations, leading to a total of **510 to 560 paediatric patients per year**

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Lessons learned



- Proton therapy is a major technological evolution of radiation that addresses the treatment needs of children, and probably adolescents and young adults, as well as of certain locations such as the eye or tumors of the base of the skull and spine. Other indications in adults should be evaluated.
- Expensive equipment, importance to limit the risk of territorial health inequities => framework agreement signed by the 3 centers in July 2018, also for shared training resources
- A limited number of proton therapy sites implies a clear logic of territorial grid with inter-hospital healthcare networks (conventions) with identified "reference centres". Short term deployment plan required.
- Pediatric cancers: site's lodging capacity for visiting families / children is an issue
- Actual costs of one session are difficult to estimate. In 2013, a flat rate for the preparation €1074 and €1017 per session was applied. Refined cost analyses are required.

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Importance to maintain and develop the experimental research capabilities of the field, including at EU level via model-based approach. Access should be broadened.

=> progress in the knowledge towards 1/ better targeting of current indications and 2/ the development of new indications

- Development of therapeutic protocols for new indications
- Need to study the long-term impact of these treatments and the persistence of their benefit/risk balance particularly on the risk for secondary occurrence of cancers.
- Need of cohort (registries) studies for long-term follow-up of treated patients, including paediatrics, with standardized, prospective collection of clinical and also medico-economic data, including costs of sequelae treatment of and secondary complications to treatments, and costs-benefits comparison of proton therapy vs carbon therapy to other radiotherapies.

=> International ETOILE cohort study sponsored by Leon Berard Center in Lyon (20 centers, 250 patients) kicked off in dec 2017

Improvement and miniaturization of equipments (radiotherapy, nuclear physics sciences)





Thank you !

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