ULICE M36 advance meeting

Report on JRA

WP2 “Clinical Research Infrastructure”

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Ulrike Mock

The ULICE project is co-funded by the European Commission under FP7
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Union of Light Ion Centres in Europe

Start Date	M1	
End Date	M48	
Lead Beneficiary	MedAustron/ETOILE	
Effort	Planned at M48: 57 m.m	
Deliverables Submitted	JRA 2.1, JRA 2.2, JRA 2.3 (M18), JRA 2.4 (M24),	
	JRA 2.5, JRA 2.7, JRA 2.8 (M36)	
Milestones	M24: "Report on a SOP for ion therapy" o.k.	
Active Delays	JRA 2.6	

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- **Review of the work done from 8/2011 to 09/2012** with comparison to the original description of work, milestones and deliverables

TASK	STATUS	WORK PERFORMED / RESULTS REACHED at M36
Task 2.4 Joint dosimetry protocol structure enabling intercomparison between centres, including modern dosimetric and microdosimetric approaches (M24)	Done	Deliverable submitted
Task 2.5 Harmonization and recommendations for prescribing and reporting absorbed doses and dose-volume histograms based on 3D and 4D concepts (M36)	Done	Deliverable submitted
Task 2.6 Implementation, testing and evaluation of the structure with typical “cases” for research and development (M36)	In progress	Deliverable submission intended end of Sept. 2012

- **Review of the work done from 8/2011 to 09/2012** with comparison to the original description of work, milestones and deliverables

TASK	STATUS	WORK PERFORMED / RESULTS REACHED at M36
Task 2.7 Document on joint outcome assessment: disease control, recurrence assessment, morbidity assessment, quality of life (M36)	Done	Deliverable submitted
Task 2.8 Designing a standard operation procedure taking into account concepts and terms as defined in WP2.1 (M36)	Done	Deliverable submitted

❑ Implementation of results and actions undertaken to date

- With the exception of JRA 2.6, deliverables have been prepared on time and provided to the whole ULICE community via internal website
- Organization of three WP2 working parties and three short meetings
  - September 1, 2011 short meeting in Marburg (before previous ULICE meeting)
  - November 24, 2011 one day meeting in Lyon (before NIRS-ETOILE 2nd joint symposium)
  - April 11, 2012 one day meeting in Vienna
  - May 9, 2012 telephone conference
  - July 2, 2012 telephone conference
  - July 3-4, 2012 two days meeting in Lyon (task 2,5)

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M36: Deliverable for Oct 2012

Detailed review by Task/WP2

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2.5/2.1 Harmonisation and recommendations for prescribing and reporting absorbed doses and dose-volume histogrammes based on 3D and 4D concepts

André Wambersie / Jacques Balosso

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- **Volume concepts in Oncology and Radiation Therapy**
- **The biology waited dose equieffective and isoeffective dose D_{EquiE} & D_{IsoE}**
- **Reporting dose at selected clinically relevant point(s) and Dose-Volume Histograms (DVH)**
- **Specific issues related to 4D reporting**
- **Introduction of some discussions about the PTV definition in particle therapy**

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2.6/2.3 Implementation, testing and evaluation of the structure with typical “cases” for research and development

Richard Pötter

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2.7/2.1 Document on joint outcome assessment: disease control, recurrence assessment, morbidity assessment, quality of life

André Wambersie / Guillaume Vogin

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Pattern of tumor relapse and "toxicogenesis" in Carbon Ion RT (CIRT)

- To provide a tools to analyse and compare relevant dose/volume parameters and their corresponding spatial dose distribution to correlate with both tumor- and OAR outcome.
- i.e. tumor relapse or OAR toxicity

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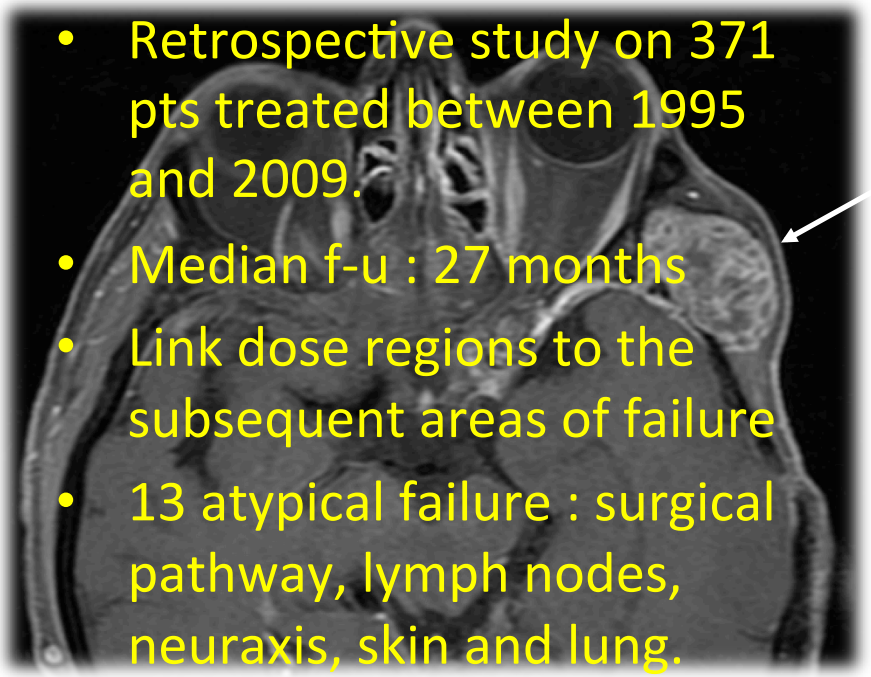
Starting point

Adaptive GYN brachy (AKH),
Schmid M et al., Radiother Oncol, 2011

- Retrospective matched-pair analysis, 265 pts treated from 1998 to 2010;
- Median f-u : 17 months
- Link low dose regions to the subsequent areas of failure
- 24 local failures;

Particles in skull base chordomas (ICPO),
Vogin G et al., submitted



- Retrospective study on 371 pts treated between 1995 and 2009.
- Median f-u : 27 months
- Link dose regions to the subsequent areas of failure
- 13 atypical failure : surgical pathway, lymph nodes, neuraxis, skin and lung.

Pattern of relapse defined according to the % of the relapse tumor volume located within the 95% isodose line on the primary RT plan. *Dawson LA, IJROBP, 2000*

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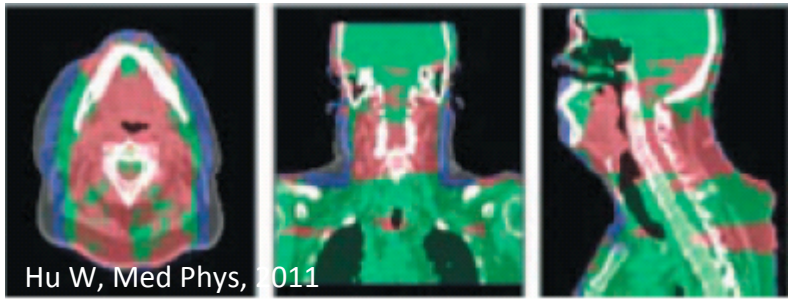
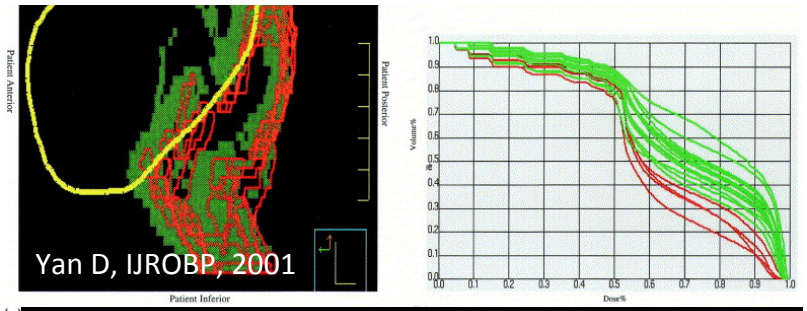
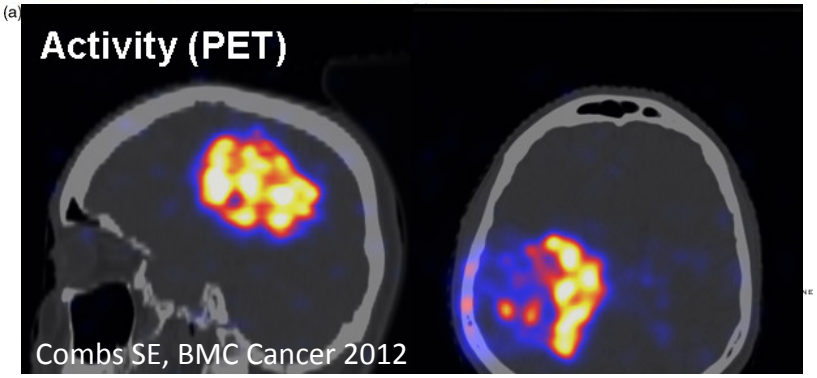
WP2.7: Perspectives

- Specific CRF adapted to CIRT outcome
- long-term retrospective studies such as matched pair analysis
- prospective studies (in case of event)







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2.8/2.2 Designing a standard operation procedure taking into account concepts and terms as defined in WP2.1

Ramona Mayer / Ulrike Mock

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- to provide a general guideline for study design
- listing the main topcis/ general structure to be considered while designing a clinical study protocol (Phase I-III)
- tool for harmonizing the structure design of clinical studies in hadrontherapy

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Prospective: M48 Oct 2013
End of ULICE

- **2.9/2.1** Integrated concept of 3D/4D absorbed dose and variations in biological effects with RBE, fractionation, overall time.

  André Wambersie / Jacques Balosso

- **2.10/2.2** Adaptation of the so far existing protocols (that will be provided by WP10) within the facilities (UKL-HD, CNAO, UNIMAR) according to the needs as defined in this SOP for clinical trial design for hadrontherapy in cooperation with WP11.

  Ramona Mayer / Ulrike Mock

- **2.11/2.3** Adaptation of the tasks and the structure according to the test phase to design and to implement the final set of tasks and structure as agreed upon.

  Richard Pötter

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- **Proposal for the next period:**

- Planned WP 2 meetings / activities:
  - September 15, 2012: short meeting in CNAO
  - December, 2012 in Wiener Neustadt, Austria
  - April, 2013 in Lyon, France
  - telephone conferences
  - others…

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Thank you

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