

ISTITUTO NAZIONALE DI FISICA NUCLEARE

GIUNTA ESECUTIVA

DELIBERAZIONE N. 9432

La Giunta Esecutiva dell'Istituto Nazionale di Fisica Nucleare riunita in Roma il giorno 18 maggio 2012

- visto il Regolamento per la valorizzazione, lo sviluppo e l'applicazione delle conoscenze dell'INFN, pubblicato nella Gazzetta Ufficiale della Repubblica Italiana – Serie generale n. 45 del 24.02.2004;
- vista la deliberazione n. 11008 adottata dal Consiglio Direttivo nella riunione del 30 aprile 2009, con la quale è stato approvato lo schema di “Cooperation Agreement” tra l'Istituto Nazionale di Fisica Nucleare e la Ion Beam Applications sa (IBA) avente ad oggetto una collaborazione ad attività di ricerca congiunta finalizzata allo sviluppo di un “Treatment Planning System” (TPS) con validazione clinica, utilizzabile per il trattamento dei pazienti con ioni di carbonio, poi sottoscritto in data 29 maggio 2009;
- visto, in particolare, l'articolo 3, lettera b) del suddetto Agreement il quale prevede il versamento da parte di IBA di un contributo a favore dell'INFN non superiore a € 225.000,00 annui, per un importo complessivo triennale non superiore a € 675.000,00, da destinare al finanziamento di contratti o assegni di ricerca per un massimo di 9 posizioni di ricercatore da impiegare nelle attività di ricerca per tre anni;
- premesso che la scadenza dell'Agreement, di durata triennale a partire dal 29 maggio 2009, è prevista per il 28 maggio 2012;
- considerato che, come previsto dall'Agreement, sono stati assegnati contratti o assegni di ricerca, nel limite delle 9 posizioni di ricercatore previste all'articolo 3, lettera b) dell'Agreement medesimo, per personale ricercatore da destinare alle attività previste dal Progetto TPS;
- vista la proposta del Direttore della Sezione di Torino formalizzata con nota del 3 maggio 2012, prot. n. 250, relativa alla richiesta di approvazione della revisione del Cooperation Agreement fra l'INFN e la IBA, per lo sviluppo di un sistema per la pianificazione dei trattamenti in Adroterapia;
- ritenuto, alla luce delle attività sino ad ora svolte, di procedere ad una ridefinizione delle attività tecnico-scientifiche previste nell'Agreement del 29 maggio 2009 nonchè di consentire ai ricercatori assunti come sopra detto di

continuare la loro attività fino al termine del loro contratto, come proposto dal Direttore della Sezione di Torino nella nota del 3 maggio 2005, fermo restando il quadro economico complessivo previsto dall'Agreement approvato con la deliberazione n. 11008 del 30 aprile 2009;

- ritenuto di dover procedere con la dovuta urgenza per consentire la formalizzazione dell'Amendment di cui alla presente deliberazione entro la citata scadenza del Cooperation Agreement;
- visto l'articolo 14, comma 5, lettera b) dello Statuto dell'INFN che consente alla Giunta Esecutiva di sostituire il Consiglio Direttivo in caso d'urgenza;

DELIBERA

- 1) Di approvare lo schema di "Amendment to the Cooperation Agreement signed on May 29th, 2009" tra l'Istituto Nazionale di Fisica Nucleare e la Ion Beam Applications sa, allegato e che fa parte integrante e sostanziale della presente deliberazione. Il Presidente, o persona da lui delegata, è autorizzato a perfezionarlo e sottoscriverlo.
- 2) Di sottoporre la presente deliberazione alla ratifica del Consiglio Direttivo nella prossima riunione, secondo quanto previsto dal citato articolo 14, comma 5, lettera b) dello Statuto.

Amendment # 1

**to the Cooperation Agreement signed on May 29th, 2009 between IBA and INFN
in relation with the development of a TPS kernel for hadrontherapy.**

Between

Istituto Nazionale di Fisica Nucleare, hereinafter called “INFN”, an Italian Governmental Agency with place of business at Via E. Fermi 40, 00044 Frascati (Italy), legal trade register 84001850589, and hereby represented by Prof. Fernando Ferroni, acting in his capacity of President of INFN and authorized by the INFN’s Board of Directors resolution of [DATE] 2009.

on one part

and

Ion Beam Applications sa, hereinafter called “IBA”, a Belgian corporation having its place of business at 3, Chemin du Cyclotron, 1348 Louvain la Neuve (Belgium), and hereby represented by Yves Jongen, Chief Research Officer and Managing Director who declares to have all necessary powers for binding the company,

INFN and **IBA** hereinafter, jointly or individually, are also being referred to as “**Party**” or “**Parties**” or “**Contractor**” or “**Contractors**”

Whereas

The Parties are having a scientific collaboration to develop a Carbon TPS ensuring a friendly user environment and fully compliant with the applicable IBA regulatory and Quality and Assurances requirements

This collaboration is established for a duration of three (3) years (Article 9 Alinea a) and entered into activity on May 29th, 2009 at the signature of the Collaboration Agreement

IBA is contributing to the activities at INFN by financing up to 9 researcher positions, maintained up to 3 years, and for which the IBA contribution does not exceed EUR 25.000/year per research position (Article 3 Alinea b)

INFN has to develop a TPS kernel which is ready to be commercially exploited, meaning that it should be fully compliant with the applicable IBA regulatory and quality & assurance requirements towards a clinical certification (Article 1)

IBA has to provide the appropriate definition of the interfaces to connect the TPS kernel into the Mosaiq-RTP system from the Elekta company (Article 2 Alinea b)

Now and based on the present context and development status of the TPS kernel, the Parties are amending the Collaboration Agreement as follows:

Amdt 1: Qualification of the deliverables

Considering the lack of available hadrontherapy facility to complete the validation and clinical commissioning, it is agreed that the expected deliverable will not be ready for medical certification. The deliverable is therefore re-qualified as follows: at the project completion, INFN will provide to IBA:

- A fully operational prototype version of the TPS kernel (so-called DEK --Dose Engine Kernel-- prototype) with the following features:
 - o DEK prototype will be capable of computing proton and carbon ion treatment plans according to the PBS treatment modality;
 - o DEK prototype will be delivered together with pre-computed lookup tables and databases required to realize the beam model; physical records contained in these databases are obtained through Monte Carlo simulations, and biological records follow from an implementation of LEM I, II, III and MKM radiobiological models;

- DEK prototype will contain a beam model derived from measured beam datasets from the Essen facility (for the proton beam) and from the CNAO facility (for the carbon beam);
- DEK prototype will handle data in proprietary formats, it will not directly support the DICOM standard; the proprietary formats will be appropriately described in order to guarantee the development of a matching interface;
- DEK prototype will allow the computation of physical and biological doses on the basis of predefined treatment plan (forward dose computing); this functionality will be assessed on the basis of geometrical and representative clinical situations provided by IBA;
- DEK prototype will allow the optimization of treatment plans (inverse computing) according to a clinical prescription imposed by the user; this functionality will be assessed on the basis of geometrical and representative clinical situations provided by IBA;
- In order to perform the plan optimization, DEK will integrate the optimization library developed by Cenaero Research Centre from Belgium;
- The complete deliverable provided by INFN to IBA will include:
 - The source code, specific binary libraries, user routines and auxiliary programs, and compiled (executable) version of all structures and methods used to populate the physical and biological databases (even if it is not meant to be integrated in the final product release, it will be needed for maintenance and upgrades of the databases)
 - The source code and compiled (executable) version of all structures and methods supporting the functionalities of the DEK as listed above, which include non exhaustively
 - The management of CT images and contoured structures;
 - The interpretation of CT information, in particular the conversion of Hounsfield Units;
 - The definition and handling of a computation grid;
 - The elaboration of a beam model which specifically matches measured datasets in any individual treatment room of particle therapy facilities;
 - The translation of the clinical objectives and constraints from the prescription into a cost function which can be handled by the optimization algorithm.

- The complete documentation corresponding to the above mentioned elements;
- The complete set of software design documents (system requirements, architecture, interface definition documents, test matrix) including the traceability between the elements of these documents
- The reports and output datasets from the different tests aiming at demonstrating that the above functionalities are available.

The acknowledgement of these deliverables and the evaluation of their quality will be measured according to acceptance criteria commonly formulated with IBA.

Amdt 2: Integration

The INFN kernel will contain an interface to external host TPS, giving the theoretical possibility to connect to any TPS product. Practically, this interface will rely only on the exchange of DICOM objects passed through DICOM approved protocols. When DICOM will fail in providing the appropriate structures and services needed by the INFN kernel, INFN and IBA will agree on the formulation of private elements. In the framework of the present contract, INFN will support and exhaustively document data handling in proprietary formats.

In the perspective of such integration, IBA is developing (in partnership with the QSpin Consultancy company from Belgium) a piece of software which manages the translation between DICOM objects and these proprietary objects.

IBA maintains a DICOM Conformance Statement (DCS) document, which describes the use of existing DICOM objects and the proposed private elements to be added in extension.

Amdt 3: Termination

Based on the signature of the Collaboration Agreement, the project is supposed to terminate on May 28th, 2012 (**'the termination date'**). However, considering the conditions of recruitment of the INFN researchers and the constraints applying on the INFN employment contracts, the Parties agree that

- all researchers recruited on a research grant paid by IBA, and having a valid research contract at the termination date, will be allowed to continue their activities until the end of their contract;
- in order to guarantee the expected quality of the deliverables, INFN may decide to recruit scientific profiles other than researchers (e.g. software developers);
- IBA guarantee the funding of these INFN contracts up to a total financial contribution which does not exceed the amount stated in the Collaboration Agreement (=up to 3*9*25.000 EUR).

In witness thereof,

the Parties have caused this Agreement to be executed in two counterparts, each of which when so executed and delivered shall be an original, but all of which shall together constitute one and the same Agreement.

Date:

For IBA

For INFN

Dr. Yves Jongen
Chief Research Officer

Prof. Fernando Ferroni
INFN President