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The Laser-hybrid Accelerator for Radiobiological Applications

Prelimary Activity 2 project plan

The LhARA collaboration

Author list to be updated.

[1] *Institute*

Executive summary

Lead authors: AG, KL

Lay summary

Lead authors: HH, GJ, PP

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A Annex: Preliminary Activity 2 Project Plan

A.1 Management plan

A.1.1 Programme organisation

The multidisciplinary LhARA collaboration's mission [1] is to harness the disruptive potential of laser-driven proton and ion sources to create a ground-breaking biomedical research facility [2, 3]. The collaboration's ambition is that the technologies demonstrated in LhARA will be transformative in the automated delivery of personalised, precision, multi-Ion Beam Therapy (IBT).

The LhARA programme encompasses the:

- Execution of the LhARA project by which the Laser-hybrid Accelerator for Radiobiological Applications will be realised;
- Development of a cutting-edge radiobiology research programme in which the novel techniques developed by the collaboration play an ever increasing role and which culminates in the exploitation of the uniquely flexible LhARA facility; and
- Generation of clinical and other impact through incremental deployment of the novel techniques and technologies developed by the collaboration.

The organisation of the LhARA collaboration has been modelled on that of a large, successful particle-physics collaboration that, in partnership with a host laboratory or institute, delivers a complex scientific infrastructure. Successful execution of the LhARA programme will generate substantial societal and economic impact. Therefore, the organisational structure includes representation from key stakeholder groups beyond the direct scientific and technology-development communities. The collaboration places great importance on maintaining the multidisciplinarity of the programme. The essential nature of the life-science/natural-science partnership is therefore manifest at all levels.

The organisational structure of the LhARA collaboration is shown in figure 1 and has the following key Boards, roles and resonsibilities:

The Institute Board represents the interests of the institutes, industrial partners, and patient groups that make up the collaboration (see figure 2 and Annex B). Each collaborating institute and stakeholder group is represented on the Institute Board. All positions of responsibility within the collaboration are approved by the Institute Board. The collaboration's spokespeople and programme managers attend the Institute Board.

The Institute Board (IB) is co-chaired by a life-scientist and natural scientist chosen from among the IB membership. The inaugural chairs of the IB have responsibility for drafting the collaboration's constitution. Once agreed, the IB will review and amend the organisational structure of the collaboration from time to time as the programme evolves.

The Institute Board reviews and approves the technical options and distribution of responsibilities among the participating institutes proposed by the LhARA Executive Board. It ratifies major strategic and technical decisions and supports the collaboration management team in the preparation of reports, funding proposals, and other documentation required to drive the programme forward.

The Executive Board provides the management of the LhARA collaboration and is responsible for the delivery of the programme, performing both an oversight and top-level management function. The Executive Board (EB) will have the authority to make cost, scope and schedule decisions. The membership of the board will consist of collaboration co-spokespeople, the IB co-chairs and the collaboration programme managers. Other expertise may be co-opted as required. The programme managers will deliver status reports on progress, finance, risks and issues at the EB. The board will meet approximately every 2–4

Figure 1: The LhARA collaboration organisational chart. The organisation structure has been defined by the collaboration to deliver the LhARA programme. The functions of the Institute Board and Executive Board are described in the text. The LhARA project is defined in the context of the overarching programme such that LhARA serves the Ion Therapy Research Facility (ITRF) [4].

weeks or as required. It has overall responsibility for managing the LhARA initiative. The EB represents the collaboration in its relations with outside bodies. The EB is chaired by the LhARA spokespeople.

The key roles in the LhARA programme management team are:

Institute Board co-chairs: The LhARA Institute Board has two co-chairs. The co-chairs are chosen from the Institute Board membership such that their expertise and experience cover the natural and biomedical science and technology development aspects of the collaboration's programme.

The present co-chairs are:

- Yolanda Prezado, Institut Curie, Paris;
- Timothy Greenshaw, Liverpool.

Spokespeople: The LhARA collaboration has two Spokespeople who jointly lead the collaboration. The spokespeople are chosen such that their expertise and experience cover the natural and biomedical science and technology development aspects of the collaboration's programme.

The present spokespeople are:

- Amato Giacca, Oxford Institute of Radiation Oncology;
- Kenneth Long, Imperial College London and STFC.

Programme managers: The LhARA collaboration has two programme managers who are jointly responsible for coordinating all technical, financial, and programme-planning activities. The programme managers are chosen such that their expertise and experience cover the natural and biomedical aspects of the collaborations programme.

The present programme managers are:

- Jason Parsons (Biological Science), University of Liverpool;
- Colin Whyte (LhARA Project), University of Strathclyde.

Figure 2: Graphical representation of the institutes that make up the LhARA collaboration. The list of collaborating institutes is reproduced in Annex B.

As the LhARA initiative gets off the ground a programme manager for the "Impact: clinical and industrial" activity will need to be appointed.

Programme administrator: The LhARA collaboration's programme administrator assists the LhARA programme management team in the execution of their functions.

The present programme administrator is:

- Dionysia Kordopati, Imperial College London.

A.1.2 Project organisation

The scope of the LhARA project is to deliver the Laser-hybrid Accelerator for Radiobiological Applications. The present proposal is being prepared in the context of the dvelopment of the Ion Therapy Research Facility (ITRF) [4] and defines the programme and resources required during the Preliminary Activity and the Preconstruction Phase.

The organisation of the LhARA project will be carried out in accordance with the STFC Project Management Handbook [5, 6] in by the LhARA collaboration in partnership with the STFC Daresbury and Rutherford Appleton Laboratories. The organisational structure of the LhARA project is shown in figure 3 and has the following key Boards, roles and resonsibilities:

The Project Management Board oversees all aspects of the facility design, schedule development, project planning and execution, cost estimation, software development, and computing matters. It serves as an advisory body for the LhARA Executive Board and LhARA Project Manager.

The PMB will be chaired by the LhARA Project Manager and include:

- The LhARA collaboration co-spokes people, one of whom will act as the Principal Investigator, the other as the Project Scientist;
- Work Package leaders; and
- Project Management Office representatives.

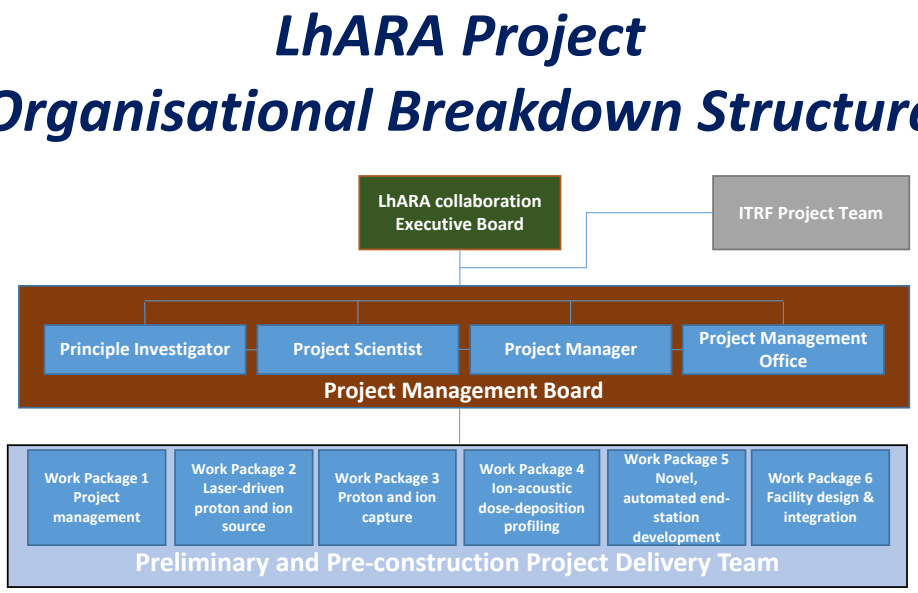

Figure 3: The organisational chart for the LhARA project. The functions of the Project Management Board are described in the text. The key roles within the project structure are indicated. The preliminary phase project is executed through six work packages, as indicated in the figure. The work content of each work package is defined in section **??** to **??**.

Additional expertise may be co-opted as required. The PMB collectively manages all aspects of the LhARA project.

The PMB will develop and maintain the LhARA Project Management Plan (PMP) will include all the plans and reference all the key project-management documentation required to deliver the project successfully. The PMP will include the specifications, scope, finance, resources, schedule, objectives and deliverables, risk management, stakeholder plan, procurement plan, quality assurance management, benefits realisation and impact plan, safety health and environment plans.

The PMB will meet monthly. Additional meetings focussed on specific technical and planning issues will occur more frequently with progress reported at the monthly PMG meetings by Work Package Managers.

The LhARA project has been underway for several years and produced a pre Conceptual Design Report [2, 3]. Further definition is proposed through the development of a full Conceptual Design Report. Technical Design Reports for LhARA Stages 1 and 2 will be produced in the Preconstruction Phase.

The Implementation Phase of the project will follow the Preconstruction Phase. During the Implementation Phase the PMB will baseline the project and adopt strict project management methodology including the management of:

- Stakeholders;
- Planning;
- Scope;
- Quality;
- Finance and Cost;
- Resources;
- Schedule;
- Change control;
- Risk and value-engineering issues;

- Procurement;
- Health, safety and environment;
- Off line assembly and testing;
- Installation and testing; and
- Commissioning with beams.

During the LhARA project's lifecycle decision gates will review and confirm the continued viability of the work. Design reviews will be implemented during the concept and definition phases of the project. The reviews will focus on: what has been achieved; what are the key requirements for the next phase; what are the key decisions to be made; and whether the business is case still viable, i.e. can the desired benefits be achieved for an acceptable level of cost and risk? Gates will also be implemented at the end of each phase of work.

The Project Management Office (PMO) provides project management administration support to the LhARA project and collaboration. The PMO will standardise the project-related management processes in support of the Project Manager, Principal Investigator, Project Scientist, and project delivery team.

Roles in the LhARA project management team have been defined to ensure appropriate expertise is brought to bear on the execution of the work. The key roles in the LhARA management team are:

The Principal Investigator: (PI) will lead the science team requirements and deliverables for the LhARA project and be responsible for the scientific success of the LhARA project.

The present Principal Investigator is:

- Kenneth Long; Imperial College London/STFC.

The Project Scientist: (PS) is responsible for ensuringn that the specifications for the LhARA beam delivered to the endstations, the beamline instrumentation, the diagnostics and endstation capability remains aligned with the scientific requirements of the LhARA user community. team requirements and deliverables and be responsible for the scientific success of the project.

The present Project Scientist is:

- Amato Giacca; Oxford Institute for Radiation Oncology, Oxford University.

Project Manager: is accountable to the LhARA Executive Board and forms the link to the ITRF Project Team. Together with the PI and PS, the Project Manager will maintain a continuous dialogue with the STFC laboratory, the collaboration and the work package managers to ensure a common understanding of the; 1work, cost, risk, schedule and deliverables. The role and responsibilities of the project manager is well understood and clearly defined in the STFC Project Management Framework [5, 6].

The present Project Manager is:

- Colin Whyte, University of Strathclyde.

Project administrator: The LhARA collaboration's project administrator assists the LhARA management team in the execution of their functions.

The present project administrator is:

- Dionysia Kordopati, Imperial College London.

The LhARA collaboration recognises the importance of independent scrutiny of its activity. Therefore, the collaboration has established the principle of formal reviews of its programme by independent experts of international standing. The first such review [7] was held before publication of the pre-CDR [2] for the facility. A committee is being established to review the Preliminary Activity and the Preconstruction Phase programmes proposed here. The recommendations of the review committee will be considered in the completion of the present proposal and the review committee's report will be made public.

A.1.3 Project specification

The R&D programme necessary to deliver a full Conceptual Design Report (CDR) for LhARA was first presented in the pre-CDR [2]. This proposal builds on the pre-CDR and is designed to establish the conditions for the technical-design phase of the LhARA project. The five-year programme defined above and summarised in the sections which follow will significantly improve the definition of the project, remove uncertainties, mitigate risks and deliver the principal milestone defined in the proposal for an Ion Therapy Research Facility (ITRF) [8] submitted to the UKRI Infrastructure Advisory Committee on the 15^{th} June 2021, namely the completion of a full CDR for the facility at the end of the two-year Preliminary Activity. The present proposal also defines the work that must be carried out in the subsequent three-year Preconstruction Phase. An overview of the schedule for the development of the LhARA initiative in the Preliminary Activity and the Preconstruction Phase is shown in figure 4.

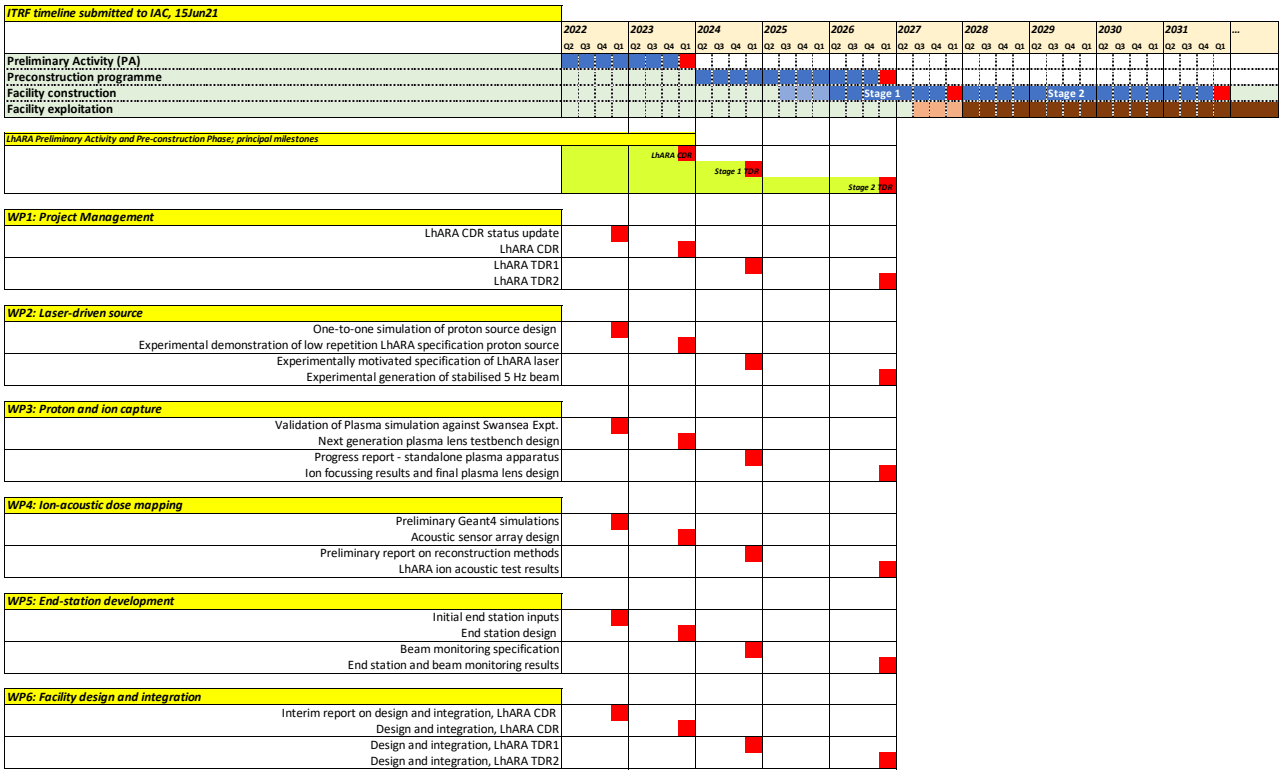

Figure 4: Waterfall chart showing the principal milestones that define the project proposed herein. The block entitled "ITRF timeline submitted to IAC, 15Jun21" shows the timeline for the development of the ITRF submitted to the UKRI's Infrastructure Advisory Committee. The block entitled "LhARA Preliminary Activity and Preconstruction Phase; principal milestones" shows the principal milestones of the LhARA Preliminary Activity and Preconstruction Phase proposed here. The subsequent blocks present the principal milestones that serve to specify each of the work packages.

The specification of the Preliminary and Preconstruction Phase programmes has been split into two streams:

Facility design and integration encompasses the preparation of full conceptual and technical designs for all aspects of the LhARA facility. The implementation of LhARA has been conceived in two Stages:

- *Stage 1*: Proton beam to the low-energy *in-vitro* end station; and
- *Stage 2*: Proton and ion beams to the high-energy *in-vitro* and the *in-vivo* end station.

Risk management encompasses the R&D programme necessary to address the principal risks attendant on the implementation of LhARA.

An overview of the project schedule is presented in figure 4. The Preliminary Activity is assumed to take place over the first two years of the project while the Preconstruction Phase is assumed to take place over years three to five. The principal deliverables that define the project are:

Preliminary Activity:

- *Facility design and integration*:
  1. Full conceptual design for LhARA Stage 1 and LhARA Stage 2 (work package 6).
- *Risk management*:
  2. Characterisation of the proton phase space produced by the laser-driven source and the comparison of the measured spectra to simulation (work package 2);
  3. Detailed design of the second Gabor lens prototype based on the study of non-neutral plasma dynamics and benchmarked simulation (work package 3);
  4. Proof-of-principle demonstration of Bragg peak localisation using acoustic signals (work package 4); and
  5. Specification of end-station diagnostics and instrumentation (work package 5).

Preconstruction Phase:

- *Facility design and integration*:
  6. Technical Design Report for Stage 1 at the end of year three (work package 6); and
  7. Technical Design Report for Stage 2 at the end of year five (work package 6).
- *Risk management*:
  8. Complete design and initial characterisation of laser-driven proton and ion source (work package 2);
  9. Detailed design and initial characterisation of plasma lens (work package 3);
  10. Design and initial characterisation of acoustic dose-profile measurement system for the Stage 1 low-energy *in-vitro* end station (work package 4); and
  11. Initial evaluation of *in-vitro* end-station diagnostics and instrumentation (work package 5); and
  12. Specification and design of high throughput automated sample-handing system for Stage 1 low-energy *in-vitro* end station (work package 5).

A.1.4 Safety, health and environment (SHE) Plan

The LhARA collaboration has adopted a "safety-first" culture. The project team will deliver the SHE management plan for the project in collaboration with the SHE representatives of each institute and the project delivery teams throughout all phases in the project lifecycle.

Safety management at the definition stage of the project will include:

- Radiation Shielding (IRR17) estimated thicknesses, material selection and construction methods;
- Personnel safety system compliance with IRR17 and Accelerator Code of Practice in accordance with IEC61508; Adopting current best practise for accelerator access control and key exchange systems, that will shielded areas to be searched prior to operation of the laser and accelerator system;
- Local Exhaust Ventilation requirements–Extract/Exhaust systems (COSHH 2002).;
- HAZoP Process outline for systems integration; and
- Emergency Lighting, Fire Alarm and Fire suppression systems.

The person responsible for managing the technical work will be responsible for producing the risk assessment and method statement (RAMS) for each task with risks in conjunction with the staff performing the work. Contractors will provide RAMS prior to work conducted that will be approved by the construction site manager, who oversees and coordinates all the multidiscipline construction work. All work on the construction site will be conducted under a permit to work system.

It is the responsibility of the LhARA management team (Project Manager and Project Management Board) to support the Work Package managers in this task and to ensure that it is done. The Project Management Board is responsible for ensuring that special issues such as radiation, the presence of magnetic fields, etc. are widely discussed and addressed and that a full safety analysis is performed.

A Project Safety Manager will be appointed to take responsibility for delivering a coherent safety case for LhARA and submitting it at appropriate times for review by STFC and/or other relevant institutions. The Project Management Group will commission independent safety reviews as appropriate where the perceived risks are considered high or to meet the eventual goal of obtaining permission to operate. The Project Management Board will be responsible for defining, carrying out, and documenting appropriate component- and system-level acceptance tests.

Final permission to operate the stages and sub stages of the facility will be based on Safety Readiness Reviews with checks and sign-off sheets by the technical leads of each discipline. Documentary evidence of adherence to the agreed safety procedures and methods, evidence of materials certification, and engineering calculations will also be required. The operation of LhARA will be based on best practise of similar complex laser-accelerator complex's managed by STFC radiation test facility processes, procedures, roles and responsibilities.

The LhARA project's influence on the environment will be a key consideration throughout the project's lifecycle. Minimising energy consumption and energy losses will be essential. Design, technology choices, and construction techniques of the building, its technical services and accelerator systems to reduce the projects carbon footprint will be crucial. Design for mitigating decommissioning impact and impact on the environment will be established during the planning stages of the project to reduce the use of raw materials and enable the re-use of the building, shielding materials and generic components.

A.1.5 Work breakdown structure

The Work breakdown structure is already well developed through the refinement of the work packages during the writing of this proposal. Work packages objectives have been broken down into several components to allow costing of the required staff effort and equipment. These will be further refined and formalised within the project once funding is awarded. The Work Breakdown Structure of the Preconstruction Phase will be developed as the formal proposal is written in the last six months of the Preliminary Activity. This will necessarily draw on expertise from all the work package managers.

A.1.6 Critical path

The LhARA project has not yet reached the construction phase and the individual work packages do not yet show sufficient inter-dependancies for the concept of a critical path to yield meaningful data. As the project moves forward and such dependancies emerge, a critical path through the project will be determined and monitored in the usual way. It is anticipated that such a critical path will not emerge during the Preliminary Activity of the project. Due consideration will be given to the critical path when the Preconstruction Phase of the project is planned. Currently we expect this work to begin at month 18 of the Preliminary Activity of the project and continue through month 24.

A.1.7 Risk management plan

The Project delivery team is required to keep the Project Management Board apprised of potential risks, their consequences and the development of appropriate contingency plans. The Project Manager and Work Package Managers will report regularly on the evolution of the project risk register to the Project Management Board. Where appropriate costs will be assigned to the risk-mitigation strategies and recorded in the risk register. "Trigger levels" will be set in the risk register so that potential problems are highlighted and reported to the Project Management Board in a timely manner. Risk Management will be a standing agenda item at the Project Management Board and Executive Board meetings. Risks will be identified, captured, have mitigation controls implemented to reduce the risk likelihood or impact (or both), and will be recorded and monitored by a Risk Register process. Risks that become an issue will be captured in an Issue Log to be monitored and resolved.

A risk analysis at the Work Package level has been performed by the Work Package managers. Project risks and the principal risks identified in the work-package analysis have been presented above. The list will be updated in preparation for each Project Management Board meeting; significant changes will be presented by the Project Managers in their report to the Project Management Board.

A.1.8 Quality assurance plan

Quality assurance will be delivered as described in the projects Quality Assurance Management Plan (QAMP) that will be written during the definition phase of the project. To assure the success of the project, the integration of quality will be critical throughout the project lifecycle. The QAMP will set the management arrangements for people, processes and tools to provide the structure for assuring that LhARA requirements will be met and the risks of not meeting requirements minimised. The QAMP will be reviewed and updated throughout the lifecycle of the project. The QAMP will include the following sections:

- Project Quality Policy, Purpose and related documents;
- Quality Management Roles and Responsibilities;
- Deliverables;
- Communication;
- Configuration Management and Change Control;
- Procurement Management and Assurance;
- Product Identification and Traceability;
- Document and Data Management;
- Software Assurance;
- Component Handling, Storage and Transportation;
- Transfer of Ownership;
- Design Reviews;
- Product Acceptance;
- Manufacturing Inspection Plans;
- Non-Conformance Management;
- Measurement and Analysis; and
- Continuous Improvement.

The Quality assurance management plan is based on the project-management methodology presented in [5, 6]. The following tools will be used:

- The evaluation through simulation of the design performance of components of the LhARA system;
- The benchmarking of the simulations against published data, measurements on model systems, and the characterisation of appropriate prototypes;

- The documentation of designs and their evaluation at appropriate intervals in Technical Notes held in the document repository described below; and
- Independent verification of engineering drawings, engineering calculations and documentation through both internal and independent design reviews.

The initial Work Breakdown Structure (WBS) has been developed and is summarised above. Of particular concern is the issue of integration; there are three levels at which particular attention to the interfaces and system integration will be given:

- The interfaces between adjacent modules;
- The internal interfaces in a module where the responsibilities are shared between different institutes; and
- The interfaces required at the time of installation and the overall integration of with the environment.

The WBS is overseen by the Project Manager and reviewed by the Project Management Board which includes the managers of the "Design and integration" work package (WP6). One of the managers of WP6 is and will continue to be an experienced expert in accelerator-system integration. This individual will take the lead in discussions leading to the identification, specification, and documentation of system interfaces within the Project Management Board.

The various bodies that form the formal LhARA management structure use action lists to initiate and track issues of design, interface, installation, and integration. Changes to the project specification, cost and schedule are also considered by the Project Management Board and in turn by the Project Management Board. A change control mechanism will be established as the project enters the Preconstruction Phase.

A.1.9 Document control plan

Project documentation, including engineering drawings and specification documents, is collected in the "Technical Note" repository [9] that is maintained as part of the CCAP wiki [10]. The documentation source files (WORD, LaTeX, figures, spreadsheets etc.) are stored in a GIT repository [11]. The GIT repository is used to maintain a detailed version history of the individual documents.

Documents are organised by category and labelled with the date, subject and revision numbers. Technical Note numbers are issued by the Project Managers and review of the content of the notes is provided by the Project Management Board and Project Management Board.

A.1.10 Staffing strategy

Initial estimates of the staff effort required to deliver the LhARA facility were presented in the pre-CDR [2]. The effort break-down in terms of FTEs needed for the different roles specified in the pre-CDR project plan are shown in table 1. These estimates are reproduced here as a guide to the scale of the undertaking. It is reasonable to assume that more effort will be needed as the table includes only those positions and rolls identified in the pre-CDR. The development of a more robust staff-effort estimate will be carried out in WP6 and presented in the CDR at the end of year 2 of the programme proposed here.

The development of the LhARA Programme, which includes the development of radiation biology and biomedical impact activities will require further staff resources to be secured.

A.1.11 Availability of staff resources

Execution of the LhARA Project will require expertise in laser-driven particle sources, high power optics, accelerator science, RF and other electrical power systems, cryogenics engineering, advanced diagnostics, detectors

Type of position	Number of FTEs
Academic	10.7
Administrative	10.3
Engineering	27.9
Post-doctoral Research associate	61.2
Post-graduate student	50.7
Technical/support	5.1

Table 1: Breakdown of the staff effort estimated as required for the execution of the LhARA project. Table taken from the Management annex of [2].

and instrumentation, advanced beamline design, experimental systems design, automation, feedback and control, high-throughput, and high-performance computing. The institutes that make up the LhARA collaboration and the STFC has pools of expertise in all of these areas.

The LhARA project and the wider LhARA Programme are significant activities. The collaboration recognises the need to develop a recruitment and staff-development strategy by which to build on the existing skill base. Of particular importance is the development of an appropriate depth of expertise at the interfaces between the existing skills sets. For example, the LhARA collaboration includes leading experts in laser-driven sources, novel accelerator development, and advanced instrumentation as well as internationally recognised radiation biologists, biophysicists, medical physicists and oncologists. For the full benefits of the programme to be realised staff with multidisciplinary expertise able to communicate effectively across the individual specialities will be required. LhARA personnel are active in the development of a number of multidisciplinary initiatives by which to create a cohort of scientists with the expertise necessary to deliver the LhARA Programme.

The novel technologies on which the LhARA design concept is based have either recently been implemented or are in the early stages of development and are being actively pursued in a number of locations in the UK, Europe and worldwide. The LhARA collaboration encompasses the key UK groups contributing in each of the novel technology-developments areas. The collaboration places great importance on its efforts to continue to develop links with strong laboratories overseas. With the resources requested in this proposal we will seek to establish further collaborations with Berkeley, SLAC, and a number of European institutes.

It will be important for all LhARA project staff to continue to develop their expertise and exchange ideas in these fast-moving areas through participating in, and organising, international workshops and collaborating on related development projects. The LhARA collaboration is well placed to do this, for instance the collaboration is active in the preparation of the ”Disruptive technologies for proton/ion oncology workshop” which will take place at RAL on the 28^{th} April 2022. There will also be great benefit to be obtained from encouraging short term visiting-scientist appointments across the collaboration, to establish student-exchange programmes, and to enhance the present CCAP seminar series to encompass areas of interest to the members of the collaboration.

A.1.12 Consideration of diversity issues

The collaboration recognises its responsibilities in the promotion of equality and diversity in the development of its activities. As employees, each member of the collaboration is responsible to their employer for their adherence to Equality and Diversity policy. Where work is being carried out outside the jurisdiction of a particular collaborating institute, the collaboration will be guided by the STFC Diversity Guide [12].

In the execution of the LhARA initiative it is necessary to distinguish a number of activities:

- Working at an individual's home institution: in this case the regulations established by the individual's employer will be in effect;
- Working on an "occasional" basis as a visitor to another institute: in this case it will be understood that the by accepting to work as a visitor, the individual has agreed to be bound by the host institutes regulations; and
- The construction, execution, and exploitation of the LhARA project: The construction, commissioning, execution, and exploitation of LhARA will be significant activities extending over a number of years. Therefore, for the avoidance of uncertainty, collaboration members will be asked to sign an agreement that they agree to be bound by the host laboratories regulations. This agreement will be modelled on that in force for visiting scientists working at CERN. The model was used effectively in providing a framework for the work of MICE collaboration members when working on STFC Laboratory sites.

A.1.13 Procurement plan

LhARA is a collaborative project, with devolved responsibilities for procurement. The overall procurement plan is established by discussion within the collaboration; the Project Management Board is responsible for proposing strategy. Collaborating institutions along with the appropriate funding agencies will develop their own procurement plan. The responsibility for the procurement of the parts of the LhARA system is to be established by MoU between STFC and the individual collaborating institutes against this plan.

A.1.14 Supplier market

The significant components, both novel and off-the-shelf will be required during the Preconstruction Phase. These will be obtained through competitive tender based on a design specification worked-out in the Preliminary or Preconstruction Phases. As part of the Quality assurance management (section A.1.8), the documentation of specifications, designs, and the design evaluation will be subjected to independent technical review prior to the initiation of the tender process.

A.1.15 Impact plan and benefits realisation

The LhARA collaboration seeks to establish an entirely new technique for the automated delivery of personalised, precision, multi-ion PBT. To achieve this novel technologies, each developed for, or demonstrated in, unrelated fields will be brought together in a single system. This LhARA programme carries significant technical risk. The high-risk approach is justified by the high level of reward and will place the UK at the forefront of the PBT field, establish UK industry as a key player in the delivery of novel clinical equipment, and allow significantly enhanced access to state-of-the-art IBT across the UK.

In addition to the long-term transformation of clinical practice in IBT, the programme has the potential to generate a substantial breadth of impact in the R&D and Preconstruction Phase:

Clinical: incremental deployment of automated on-the-couch patient-imaging and patient-positioning systems and development of fast, optimised treatment-planning software. Definitive in vitro and in vivo biological measurements that will be used to enhance the accuracy of treatment planning software in the short, medium, and long term.

Technological: Prototypes of novel accelerator technologies, novel real-time "proton-acoustic" dose-deposition imaging; automated robotic systems that can be developed for clinical application, optimised image-processing and treatment-planning systems, and a simulation of the full clinical facility to be used to

optimise its efficacy and to inform its development, construction, and operation. Exploitation of the biological facility and incremental development of the novel technologies.

Industrial: The R&D prototypes and components of the various proof-of-principle (PoP) systems will be developed and produced in partnership with the industrial members of the collaboration. Active involvement in the R&D, PoP, preconstruction, and construction activities will position UK industry to take a leading role in the implementation phase.

Scientific: Direct scientific impact will be generated in the fields of laser-driven acceleration, imaging, instrumentation, diagnostic-technology, and software-system development during the initial R&D phase. Scientific impact in the field of biology will be delivered during the PoP phase. Key technologies developed and proved in operation can be spun-out to accelerator-based infrastructure for science and innovation. Execution of the proposed programme will maintain and enhance the UK's internationally recognised position of leadership in the provision of intense, pulsed ion beams.

This proposal includes a robust Stakeholder development plan (see section **??**. The early engagement with all stakeholder groups will allow opportunities to deliver impact to be exploited as the project evolves. The development of proposals to spin-out elements of the LhARA technology-development programme to benefit patients through the incremental enhancement of clinical IBT facilities the collaboration will expand its intellectual impact and attract additional investment into its core programme. Regular stakeholder consultation will inform the development of the R&D programme and the impact-generation activities of the collaboration.

Through the stakeholder-engagement activities a benefits-realisation plan will be developed during the Preliminary Activity and implemented during the Preconstruction and subsequent construction phases. Maximising the potential for the LhARA initiative to generate impact at all stages of its development is a high priority for the collaboration.

A.1.16 Evaluation strategy

The evaluation of the designs for the various components and sub-systems will be through careful and systematic evaluation of simulations, comparison of the results of simulation with measurements made on appropriately specified prototypes, and beam tests. The technical evaluation that ensures that components meet their specification will be through design review prior to production and the implementation of QA and QC procedures documented and agreed prior to the production and receipt of the item. The evaluation will be carried out through specialist sub-group meetings, collaboration meetings and, where appropriate, the simulations, measurements, and conclusions drawn will be subjected to external expert review.

The progress of the project will be carried out using the appropriate project management tools to the standard defined in [6]. The tools will include Gantt and slip charts, milestone tracking, the routine review of the project and work package risk registers, and wherever possible earned-value analysis. Appropriate risk escalation and contingency management processes will be agreed with the funding agencies at the start of the Preliminary and Preconstruction Phases.

A.1.17 Monitoring and reporting

The LhARA collaboration meets by video every fortnight to review the status of the initiative in general. In addition to status reports from the Work Package managers particular scientific or technical contributions are regularly made. Both the Project Management Board and Project Management Board meet fortnightly; the individual meetings taking place on alternate weeks. Details of the development of the project, the evolution of cost, schedule, and risk are addressed in the Project Management Board meetings, the Project Management Board providing oversight and taking responsibility for organising formal technical and scientific reviews.

In addition to the regular fortnightly meetings, the collaboration has begun to establish a pattern of plenary, in person meetings. The objective will be for a plenary, in person, collaboration meeting to take place at least three times a year. The transition to a regular in-person meeting pattern will depend on the collaboration's success in attracting resources and the development of the Covid-19 pandemic.

A.2 Revision history

Draft 0	01 August 2023	Skeleton.