MERLN Institute for Technology-Inspired Regenerative Medicine

Assessment report

EXTERNAL PEER REVIEW

2014 - 2020

December 2021

Preface

This report summarises the findings of the external Review Committee of the MERLN Institute for Technology-Inspired Regenerative Medicine at the Faculty of Health Medicine and Life Sciences, Maastricht University, which was carried out between October 27rd - 29th 2021. In addition to discussions with colleagues from the university, the review process benefited greatly from the extensive preparation undertaken by MERLN and from the provision of information in a standardised and digestible format. The Review Committee appreciates the professional assistance provided by the whole MERLN team. We also thank Maastricht University and MERLN administration, staff and PhD candidates for their contributions in making the review an interesting, informative and rewarding process.

December, 2021

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1. Introduction

This report presents the results of the assessment of the research and educational programs of the MERLN Institute for Technology-Inspired Regenerative Medicine over the period 2014-2020, conducted in October 2021 by an external Review Committee. MERLN is a research institute at the Faculty of Health, Medicine and Life Sciences (FHML) at Maastricht University and part of the Maastricht University Medical Centre+ (MUMC+).

2. The Review Committee

To assess the research and education (both at the Master's and PhD level) conducted at MERLN, an international external Review Committee was appointed by the Executive Board of Maastricht University on April 6th 2021. The Review Committee consisted of the following members:

- Prof.dr. Gerjo van Osch, Erasmus MC, Rotterdam, The Netherlands (chair)
- Prof.dr. James Kirkpatrick, Universität Mainz, Germany
- Prof.dr. Gijsje Koenderink, TU Delft, The Netherlands
- Prof.dr. Liam Grover, University of Birmingham, United Kingdom
- Prof.dr. Maria-Pau Ginebra, Universitat Politècnica de Catalunya, Barcelona, Spain
- Dr. Arnold Boersma, DWI-Leibniz Institute for Interactive Materials, Aachen, Germany
- Dr. Cristianne Rijcken, Cristal Therapeutics, The Netherlands
- Aref Saberi (PhD candidate), University of Eindhoven, The Netherlands
- Dr. Roelinka Broekhuizen, secretary, The Netherlands

Due to COVID-19, Prof.dr. James Kirkpatrick participated in the review online.

All members of the Review Committee signed a statement of impartiality and confidentiality. Additional information on the Review Committee members and their brief curriculum vitae can be found in Annex 1.

2.1 Scope of the assessment and documentation

The Review Committee used the methods described in the Strategy Evaluation Protocol 2021-2027 (SEP). This protocol aims to ensure a transparent and independent assessment process (see Annex 2: Criteria of national protocol SEP).

The Dean asked the Review Committee to

1) Assess the MERLN Institute as a whole
    a) By judging the performance of MERLN on the three SEP assessment criteria below:
        i) Research quality
        ii) Relevance to society
        iii) Viability
    b) By incorporating four specific aspects:
        i) Open Science: availability of research output, reuse of data, involvement of societal stakeholders;
        ii) PhD Policy and Training: supervision and instruction of PhD candidates;
        iii) Academic Culture: openness, (social) safety and inclusivity; and research integrity;
        iv) Human Resources Policy: diversity and talent management.

2.2 Working procedure of the review committee

The assessment was based on and supported by two main components of evidence:

- self-evaluation reports detailing the operation, management, research activities, outputs, and SWOT analysis of the research institute; these self-evaluation reports were written in the format prescribed in the national standard evaluation protocol;
- discussions with boards, managers, principal investigators, heads of department, PhD council, postdocs and junior and senior academic staff about the information provided.

The site visit was undertaken during the period 27-29 October 2021 and consisted of a number of components, which can be summarised as follows (full programme in Annex 3):

- A plenary introduction to FHML and MUMC+ by the Dean of the Faculty of Health Medicine and Life Sciences Prof. Annemie Schols and to MERLN Institute by the Scientific Director of MERLN Prof. Pamela Habibovic and the financial director Sef Janssen
- Introduction to the three departments
- Site visit to MERLN laboratories
- Poster viewing and discussion with PhD students and postdocs presenting them
- Meeting with PhD coordinator, PhD representative and junior investigators
- Meeting with senior investigators
- Meeting on MSc and MSc programs, including talking to MSc students
- Meeting on collaborations with clinics, chief Business Development officer and Brightlands Maastricht Health Campus
- Final meeting with representatives of FHML board

The review committee had the opportunity to interview all layers of the hierarchy in MERLN, from MSc students to Dean. MERLN had carefully assigned tasks to most of its employees, either being present at informal moments, interview or poster session.

The visit was concluded with a short oral feedback session of the findings of the Review Committee, attended by MERLN staff, FHML board representatives and the scientific director of MERLN.

The draft report was presented to the dean of the Faculty of Health, Medicine and Life Sciences to redress any (factual) errors.

3. Brief description of MERLN Institute for Technology-Inspired Regenerative Medicine

The MERLN Institute for Technology-Inspired Regenerative Medicine is a research institute at the Faculty of Health, Medicine and Life Sciences (FHML) at Maastricht University (UM). As such, MERLN is also a part of Maastricht University Medical Center Plus (MUMC+), a partnership between FHML and Maastricht University Medical Center.

MERLN operates in the field of regenerative medicine (RM), a biomedical sciences branch that is focused on developing therapies to treat damaged and diseased tissues and organs. MERLN's activities are inspired and driven by advancements in technology.

The founding partners of MERLN are Prof. Clemens van Blitterswijk, Prof. Jan de Boer, Prof. Pamela Habibovic, Prof. Lorenzo Moroni and Prof. Roman Truckenmüller, who relocated their research groups from the University of Twente in 2014 to start a new institute in Maastricht. MERLN currently has around 130 employees

4. Organization and governance

4.1 Governance and organization

The governance system within MERLN is very good. The departmental structure that was presented within the self-evaluation was clear and the rationale behind the chosen structure was further clarified in the meeting. All staff members clearly feel primarily part of MERLN. The division in departments has largely an organisational role and the heads have freedom to organise their departments as they want. The department heads meet regularly and all principal investigators (PIs) are involved in all major decision-making processes and feel well acknowledged. The review committee noticed that several staff members were not aware of the organization in the research themes as defined in the report. The organisational structure has been naturally formed as the institute grew. Currently, MERLN is led by the group together, albeit the review committee suggests to share and formalise the governance structure (including decision and continuity protocols), as in cases of major disagreements it might be unclear who determines on the scientific strategy, evaluates to protect the 'boundaries' and/or the focus and who defines what to stop or not pursue.

4.2 Leadership skills of management

MERLN is clearly managed remarkably well by the academic staff who, as a team, have managed to create an extremely supportive and well-resourced environment. The scientific director has oversight of the strategy for the grouping of academics, and is well-respected within MERLN. The department heads that sit under her have their own operating budgets and oversee the development of the staff that report to them. The junior staff seemed to be uniformly happy throughout the institute and seem to be provided with everything they need to develop their careers. Each of the academic leaders within the research institute are highly respected in their own fields, taking significant leadership in learned societies (ESB, TERMIS). While in these positions, they have brought major international conferences to Maastricht, and it cannot be underestimated how important this has been to augmenting the profile of the institute, faculty and university.

One comment that the review committee may have is that the leadership does seem to be pushing against the faculty. Evidence of this includes the tendency of MERLN to push forward progressive policies without involving the university. One such example of this is the implementation of a new tenure track policy. The second such example is the fact that the institute needed to set up its own website in order to get the results that they wanted – the university system was not considered appropriate. While it is important to have trailblazing activities within an institution (and MERLN is certainly one of these), its movement ahead of the faculty has caused some issues related to promotion of staff (see paragraph 8.2). The review committee recommends that MERLN maintains a constructive dialogue with the faculty since better communication may allow the adoption of best practises across the faculty as well as prevent some of the administrative disconnections.

4.3 Academic Culture

The review committee is impressed by MERLN's open, inclusive and safe academic culture. MERLN has actively invested in this culture in several ways. They perform annual surveys and discuss the results in an institute-wide round table meeting where the staff jointly decides on necessary actions, which are implemented by forming task forces with volunteers from all across the MERLN staff. These task forces empower all the staff at MERLN to contribute their knowledge, skills, and ideas, for instance to organize events on career development and public outreach. The closely knit social

structure of MERLN further contributes to the open culture, with social activities at all levels (group, department, institute) and a buddy system for new PhD students that was initiated during the Covid pandemic. The collaborative culture also adds to the open and inclusive academic culture. Most PhD students and postdocs collaborate across the research groups and departments and are co-supervised by two or more PIs. The collaborative atmosphere is further boosted by the activity-based open-plan office, and the workflow-based labs. An elected PhD representative from MERLN connects MERLN PhD students to local confidential advisors and contributes to enhanced inclusivity and diversity policies at the faculty level through the faculty PhD committee.

The review committee felt that, on-the-whole, the academic culture in MERLN was excellent. The department heads lead their divisions by example and are individually excellent, and the more junior members of staff are clearly developing their own strong records of research and innovation. There are concerns about the academic promotion pathway (discussed in section 8.2) and in the short term, there is a feeling that some junior staff have missed opportunities for promotion and it is critical that this is addressed at a high level to prevent loss of staff. It was notable that MERLN is supported by some exceptional and innovative administrators and support staff, but it was also clear that additional administrative support for staff would be welcomed.

5. Research

5.1 Research quality

MERLN focuses its research on the development of technologies for Regenerative Medicine (RM). In all of the leading performance indicators, the MERLN Institute has proven its international competitiveness. Its numerous collaborative publications are overall of the highest quality and enjoy widespread citation, both in the biomaterials and in the RM communities. These publications underline the diversity of the fields represented in MERLN, as well as the strong collaborative activity established among the partners. There are publications in the leading journals covering biofabrication, biomaterials in the RM field (including osteoinductive ceramics and nanomaterials), micro- and nanofluidics with special focus on screening applications and models for organ-on-chip and disease-on-chip, as well as development of tools to understand fundamental mechanisms in cell-cell and cell-matrix interactions with a view to improving RM approaches.

International recognition has been crowned by the awarding of the meeting of the International Society for BioFabricaton (ISBF) in 2015, the Conference European Society for Biomaterials (ESB) in 2018 and the World Congress of Tissue Engineering & Regenerative Medicine International Society (TERMIS) in 2021 to Maastricht. In the past years the ESB meeting has become one of the most important international biomaterial conferences worldwide, and attracts many colleagues from the North American continent and the Australasian countries. As President of the ESB, Prof. Habibovic has, along with the ESB Council, done much to promote this internationally, for example, by having invited plenary and keynote speakers of the highest calibre from around the world. Similarly, the TERMIS World Congress, chaired by Prof. Moroni, is the premier event in the RM sector and attracts many clinicians as well as fundamental researchers in the field. As is the case for the ESB conferences, TERMIS draws on the world's leading experts as speakers. The fact that Maastricht has been able to attract both of these major congresses speaks for the world-class scientific standing of the MERLN Institute as well as the positive surrounding infrastructure of the university and the city.

The research quality was high as expected. To further improve the research quality, the review committee would like to stimulate the institute 1) to continue to closely monitor the overall coherence of the research portfolio, which is quite broad and 2) to ensure close connections with clinical experts to guarantee clinical translation of the technology-driven solutions they develop.

5.2 Open Science

The importance of Open-Science was clear and well emphasised through the visit. The institute has recently implemented an impressive e-lab book system that allows for groups to pool expertise and potentially share best practice wider in the community. This excellent lab book system should be considered for adoption across the faculty. The review committee recommends to consider implementing a process to allow for the routine sign-off of paper versions of the lab-book in the event that they are needed to protect intellectual property. There is a strong move towards making all data openly available and the systems are being put in place to enable this to as great an extent as practically possible. At the point this becomes standard, the institute should make sure it educates staff on the importance of keeping some data confidential in order to ensure that intellectual property can be protected.

5.3 Research integrity

The review committee finds that MERLN pays close attention to research integrity. From discussing with the staff across the institute, it is clear that a high value is placed on academic integrity and every single person that the review committee spoke with confirmed that the importance of academic integrity is emphasised by senior staff. A course in academic integrity will be implemented in the coming year and the review committee is very supportive of this going forwards.

To help ensure a high quality of the research, the institute has structured meetings at the group, department, and institute level where research plans and data are discussed, although there are some differences in the regularity of these meetings among departments and groups. The review committee recommends that regular structured meetings with all PhD students and postdocs are stimulated across the whole institute to ensure that data are discussed in all stages of research projects, incl. raw data.

The institute has recently implemented an institute-wide data base for protocols, standard operating procedures, and laboratory techniques. The four experienced lab managers further ensure consistent high quality training of researchers in the lab. To help ensure data integrity, MERLN has appointed a data steward who has implemented an institute-wide electronic lab notebook to have a uniform approach to documenting experiments (2019), and who supports the researchers with data collection and archiving in line with the FAIR policies.

The multidisciplinary research at MERLN typically requires collaborative work, which can raise ethical dilemma's related to authorship. During the site visit, the review committee found that the PIs as well as the PhD students and postdocs are fully aware of this issue and tend to openly discuss authorship distributions, sometimes even in advance. The review committee recommends that MERLN adopts and communicates a clear policy on what constitutes an authorship and promotes exchange of best practices among its three departments.

FHML is currently in the process of drafting an integrity policy for which a new committee was installed in 2018. A PI of MERLN is chair of this platform since the first half of 2021. This new committee will advise the faculty board and the schools on integrity policies and plans to establish systems to ensure integrity. MERLN is also drafting its own policy with postdoc and PhD representatives involved. All new employees already sign a university statement about integrity. From next year, there is a mandatory integrity course for all students and staff.

6. Societal relevance

MERLN aims to assure effective research translation, actively connect to the business community, establish relevant collaborations, and stimulate the entrepreneurial mindset of its scientists. MERLN uses the infrastructure of Brightlands Maastricht Health Campus and the experience of senior scientists in its translation efforts. A number of staff at the research institute expressed frustration about the level of support to help them move their innovations towards clinical and commercial application.

The MERLN Institute contributed to publications that aimed to adjust research practices and improve reporting in biofabrication, as well as a paper that led to an adjustment of Covid-19 policies. Although the unit did not produce many of such publications for societal target groups, those that are present are highly impactful and effective. MERLN aims to share its knowledge through communication and public outreach activities in an effective manner. Its communication strategy is to use various levels and modes of outreach and utilize an outreach task force.

6.1 Patents and facilitation of research translation activities

The MERLN Institute generated four patents (and submitted six more in the last two years). The number of patents is not high knowing MERLN's central aim to effectively translate research into clinical applications and product development. The institute generated a single spin-off company, which is focused on treating type I diabetes, named Lighthouse Biomedical BV. The limited number of patents and spin-off activities is, in part, a consequence of the young age of the institute (six years). As the number of patents is limited, increasing the number of (viable) patents (or patent collections) will improve the translation to spin-out. The institute follows a strategy to achieve effective translation involving relevant collaborations and networks, and making scientists aware and educated on translation.

An alternative strategy to generate effective translation and income would be out-licensing patents. MERLN has managed to out-license one patent obtained based on the work done in the Twente period (patent on 'in situ tissue engineering') to Vacis of Brightlands Maastricht Health Campus. The choice between licensing and establishing a spin-off requires careful alignment of the valorisation strategy. The knowledge transfer office of Brightlands Maastricht Health Campus and MERLN PIs do not fully align on the potential value of research findings for patenting and valuing the relevance of a patent for spin-off activities. A misalignment of expectations on the approach and amount of assistance by the Brightland Maastricht Health campus infrastructure is present. To align expectations, improved and earlier communication between the MERLN and the Brightlands Maastricht Health Campus may result in a more effective translation strategy. More support is imperative to help MERLN in translating their findings. One possibility, in the spirit of MERLN, could be to consider the establishment of a task force including input from all stakeholders and also to involve experienced medtech entrepreneurs, in order to make realistic plans together (incl. GAP analysis, trainings etc.) and evaluate/adjust along the way.

Through reading the main body of the self-evaluation, it was not clear that there was strong integration with clinicians. When discussing this with the institute leads, however, it was clear that the research undertaken by the institute is increasingly connected to clinicians. A limited number of technologies are currently applied in the clinic, which is in part a consequence of the young age of

the institute. Moreover, many collaborations have started more recently, and their effectiveness cannot be judged as of yet. The review committee suggests that the institute could feature these connections more publicly and it could be wise to make joint/honorary appointments of key clinical staff to advocate for them and to strengthen the connections.

6.2 Public outreach

The outreach to the general public through MERLN is exceptional and the team should be commended for this. The institute has clear examples of research products (publications) that public media have used, which received attention, including citations in patents and national policy documents. In this regard, the institute is effective in its outreach. MERLN scientists of all levels of seniority have been highly active in outreach in various forms of output such as public lectures, teaching, and interviews. An installed task force for outreach efforts that consists of PhD students performs regular outreach efforts of which questionnaires after the event measure the effectiveness. Feedback after the outreach event is highly commendable to maintain an effective outreach strategy. One of the things that the review committee missed was the involvement of patient groups in MERLN's research. This is something that happens as standard in other places and should be considered. It is without doubt that patient involvement in the development of the research also helps the transition of technologies to the clinic and product translation.

6.3 Visibility

Next to the visibility generated by the organisation of international conferences, the MERLN Institute has an excellent website and Twitter account that provide good visibility. The review committee recommends assessing whether the current reach of the social media portfolio provides sufficient exposure to important societal target groups such as potential users or corporations. For example, platforms such as LinkedIn may reach a more relevant professional base.

7. Education

Education is an integral part of MERLN's mission, which is "to become one of the world's leading research institutes in the field of regenerative medicine (RM) by combining high-quality creative research with training the next generations of interdisciplinary scientists". From the beginning MERLN has been engaged in a variety of education activities, including the Bachelor and Master degrees offered by both the Faculty of Health, Medicine and Life Sciences and the Faculty of Sciences and Engineering. It is worth highlighting the track on "Regenerative Medicine" in the Biomedical Sciences Master degree, that was set up by MERLN in 2017. The fact that all MERLN staff, from PIs to postdoctoral researchers and PhD candidates, are involved in one way or another in educational activities is seen as a positive aspect. The review committee, however, has detected some concern among PIs about the need to increase educational activity from 30 to 50%, and this is an aspect that should be followed up to ensure that it does not cause an imbalance into the institute's activity.

7.1 MSc education

Education is one of the four pillars on which its growth strategy for the next six years is based. In this respect, the plan to implement a Bachelor degree in Regenerative Medicine and Technology in 2022 is well aligned with the prospects of the Faculty of Health, Medicine and Life sciences of the University of Maastricht, and is regarded as a good way to attract young talent to MERLN, in addition to being a source of income for the institute and helping to achieve sustainable growth. In the long term, it is envisaged to continue the training path with a Master's programme. The review committee underlines the great value of this proposal, as it can have a more direct link to the doctorate and be a way to retain young talent. However, securing the necessary infrastructure and lab space for this program will be critical (see also paragraph 9.1).

7.2 PhD Policy and Training

MERLN offers PhD candidates the possibility to receive a very high level of scientific training, covering scientific aspects, valorisation, translational aspects, scientific communication and soft skills. In addition, from the written self-evaluation and the discussions that the review committee had with PhDs, postdocs and others, it was clear that the MERLN Institute has made remarkable efforts to invest in a collaborative environment within the institute. All PhD students and postdocs are co-supervised by two or more supervisors from different departments within MERLN and/or clinical partners. There is a great focus on collaboration within and outside the institute which helps the PhD candidates and postdocs gain exposure to other disciplines and expand their knowledge and networks. Despite the abovementioned laudable efforts and the emphasis on collaboration in the institute, the review committee felt that the levels of creativity and critical thinking of some of the PhDs and postdocs could be strengthened. This will further serve the mission of the institute to train next-generation interdisciplinary scientists. The institute might stimulate more bottom-up collaborations initiated by the PhD students and postdocs themselves, which in turn will stimulate both the creativity and critical thinking of the junior scientists and contribute to their academic development.

PIs across different departments of the institute have different supervision plans ranging from frequent one-on-one meetings to sub-group meetings and/or department meetings. Overall, the PhDs and postdocs seemed satisfied about the level of support and supervision they are receiving. However, the review committee has noticed that the PhD trajectories in the MERLN institute on average take substantially longer than four years (although the numbers may be skewed due to delays caused by lab availability in the beginning, and the Covid pandemic). The review committee

could not come to any clear conclusion regarding the reason behind this, since the work of MERLN's management team to investigate and address this issue is ongoing. To this end, the institute uses the Faculty PhD Track system and annual assessment reviews. However, the review committee recommends a closer and more frequent assessment plan as well as more flexible graduation requirements. The latter could increase efficiency as well as create opportunities to promote scientific creativity as well. The review committee is impressed by the great focus of the MERLN Institute on the wellbeing and personal growth of their PhD candidates and postdocs. Overall, from the very open discussions that the review committee had with the PhDs and postdocs, the review committee has noticed a remarkably inclusive, diverse (more than 80% international PhD candidates) and familial environment in the MERLN Institute where the PhDs and postdocs feel safe and satisfied.

8. Human Resources Policy

8.1 Diversity

The review committee was impressed by the high diversity of the MERLN staff (~130 total) in terms of cultural backgrounds and nationalities (~40 countries), age (master students, PhD students and postdocs in a 2:1 ratio, and support and academic staff of all levels of seniority), and disciplines (engineers, biologists, medical doctors, chemists, physicists). The gender diversity is quite representative of the field, with 50% of PhD candidates and postdocs being female and 30% of the principal investigators. However, the female principal investigators are currently more highly represented at the assistant professor level (3) than at the senior level (1 associate professor, 1 full professor) and only one out of four members of the executive team (the Scientific Director) is female. To retain the four talented female PIs who are currently at assistant or associate professorship level the review committee recommends MERLN to prioritize alignment of their Academic Track Development System with the HR policy of FHML (see 8.2 Talent Management). The review committee also recommends to implement measures for structural support for PIs during and after parental or extended care leave. To further enhance the gender and ethnic diversity of its academic staff, for instance by actively scouting candidates through the extensive network of the PIs, the review committee recommends MERLN to develop concrete strategies to leverage the opportunity offered by the LINK2.0 incentive.

8.2 Talent Management

Annual monitoring of the functioning of the scientific director and the full professors within MERLN is formally embedded in the HR system of Maastricht University, involving the FHML Board. Talent development of PhD students is well-embedded in the faculty, which offers a faculty PhD Track System. Talent development of postdocs entails annual assessment interviews with the supervisory team, access to courses and trainings organized by the faculty and by MERLN, and support from Maastricht University to write personal grants. Postdocs and PhD students seem to be treated similarly and the review committee advises that MERLN develops a more concrete vision on training and career development of postdocs and considers instigating a faculty postdoc committee with a link to the faculty board (similar to the existing faculty PhD committee). For the support staff, the MERLN Institute has implemented creative measures for talent development: the lab managers are given autonomy to spend 20% of their time on activities they select themselves.

For the assistant and associate professor, the MERLN Institute established their own Academic Track Development System (initiated in 2016). The review committee was impressed by this effort of the MERLN Institute to pro-actively develop and implement innovative policies for talent development, which are currently in the process of being adopted more widely across Maastricht University. The Academic Track Development system entails building up an academic portfolio that is structured in line with the new national “Recognition and Rewards” program. It shifts the focus away from quantitative elements by replacing a list of metrics by a list of competencies that can be adapted to the researcher’s profile. This system incentivizes the staff to develop a wider range of activities than just research and education, and enables diversification of career paths. It furthermore entails a sounding board that monitors progress and advises on development and promotions. From the very open discussion with the assistant and associate professors, the review committee finds that they greatly appreciate the Academic Track Development system but experience some difficulties in getting promotions due to a mismatch with the promotion procedure of the FHML faculty. To prevent a loss of talent, the review committee recommends MERLN to prioritize alignment of their

Academic Track Development System with the HR policy of FHML. Finally, the review committee encourages MERLN to actively utilize opportunities offered by the Top Talent program of Maastricht University to enrol their PIs in acceleration programs towards professorship.

9. Infrastructure and Financial position

9.1 Infrastructure

MERLN has established, in the six years of operation, high-end facilities, in line with the institute's vision based on *sharing of knowledge, infrastructure and ambition*. Specifically, it has developed a series of cutting-edge technology platforms including biomaterials, biofabrication, micro- and nanotechnology and -fluidics, and cell and tissue engineering, applicable in different clinical fields and with a great potential for research translation. This is a clear strength of the institute, and the definition of the development and consolidation of these technology platforms as one of the pillars of the strategy of growth for the next six years is considered as highly relevant, as it is expected to foster industrial collaboration and research translation activities.

The institute has a large open office space with shared facilities as well as a separate meeting room. The labs are in a different part of the building and spread over three floors. Although the institute is well equipped, a shortage of space is detected both in office and in the laboratories, especially in some laboratories such as the cell culture rooms, due to the growth in the number of researchers in recent years. This lack of space is likely to become more acute if, as is foreseeable, new equipment is obtained from funds raised by PIs in competitive projects, and especially if there is further growth in staff. The implementation of the new Bachelor degree may also exacerbate the space needs of having to accommodate Bachelor students for their research projects. The office space, with an open configuration, contributes positively to interaction and collaboration between researchers. However, from the open discussion with PhDs, postdocs as well as other personnel, the review committee identified the need to progressively adapt the space to the growing number of researchers, as well as the desirability of offering spaces that, while maintaining the advantages of the open configuration, could provide more desk areas that offer privacy.

9.2 Finances

While MERLN has some baseline funding from Maastricht University, its activity and sustainability depends heavily on fundraising by the PIs in competitive calls. Although this may imply some uncertainty about the availability of such funds, the track record in recent years shows a great capacity to attract funding in both national and European calls, which have increased from year to year, this being one of the strengths of the institute. This offers guarantees for the financial sustainability of MERLN in the coming years. The growth strategy foreseen for the coming years includes a specific and well-defined plan for attracting resources linked to the new PI figures in the new strategic lines. On the other hand, the plans for growth in educational activity, with the launch of the new Bachelor degree in Regenerative Medicine and Technology, are also expected to contribute to consolidating the institute's position from a financial point of view, by securing the financing of permanent staff. The convenience to secure some funding to increase stable administrative and technical support positions may be evaluated, as part of the growth plan.

10. Viability of the unit

The MERLN Institute was established only in 2014. It is very impressive what has been achieved since then, both in view of scientific progress and output as well as organisational infrastructure. Probably, an essential success factor hereto is the ambitious, eager and supportive mindset as is noticeable in all layers of the organisation. Besides, interactions amongst all disciplines is truly stimulated, and no boundaries between the formal three departments are noticed. New members including students obtain in-house training by supportive staff and research colleagues, whereby protocols are established to describe various topics, to assure quality and knowledge capture. There is much support, scientific freedom and open discussions. The frequent interactions both on professional as well as fun levels are valued. Senior investigators feel pleasantly independent (albeit supported when needed), involved in decision making and offered plenty of opportunities.

The excellent research funding of MERLN is seen not only in the continuing national support but also in the many successes in the highly competitive European scene, as demonstrated by major grants from the European Research Council (ERC) and by the participation in a broad spectrum of European Community consortia. This is coupled with an excellent network with leading colleagues in the biomaterials and RM fields in Belgium, Italy, Spain, France, Germany, Switzerland, Portugal, Ireland and the United Kingdom. Nationally, MERLN's activity begins in the Medical Center in Maastricht with a number of collaborations, both with conservative and surgical specialities, and continues with interactions with leading centres in the Netherlands, including Amsterdam, Eindhoven, Rotterdam, Leiden and Nijmegen.

MERLN has clear growth ambitions, both from educational as well as research and clinical translation perspective. For the planned growth of the institute the review committee advises the lead of MERLN to make the future plans more clear. These were minimally elaborated, and considered vague. Since the past six years has provided a solid basis, comprise plans with tangible milestones (including evaluation moments) as well as back-up options in case of any structural research, education and/or personnel changes are to be expected. The laboratories are very well equipped but due to the growth in the last years, they are now fully occupied. The plan is to host more students with the plans of the new Bachelor. Anticipated growth of the institute is not possible in current labs and possibilities for more space are not yet clear. Finally, for sustainable growth, the current mismatch in promotion procedures at MERLN and the faculty, substantial increase in education-related activities, dedicated task forces, and limited administrative support of younger PIs should be addressed and monitored to prevent losses with potential large implications on the research quality as well as finances (less education and/or grant acquiring).

MERLN is embedded in the FHML faculty. The collaboration with the medical center appears strong by supporting future PI positions. To further strengthen embedding in the local infrastructure, tuning the communication and activities with the faculty and Brightlands Maastricht Health Campus seems advisable. We further suggest investigating a potential collaboration with another institute (e.g., the M4I institute) regarding shared infrastructure and exchanging knowledge of the local infrastructure. There are different perceptions when it comes to valorisation. Whilst the campus and faculty have high ambitions, scientists find it often challenging since this is on top of all other responsibilities, whilst there are no streamlined processes, there is insufficient support and a mismatch in expectations between MERLN members and, Brightlands Maastricht Health Campus and TTO. It is the review committee's opinion that if "valorisation" is considered an important performance criterion, the support that is provided should be reconsidered and the expectations from both sides

need to be better matched. The faculty can clearly benefit from the pro-active approach of MERLN such as regarding their Talent program as well as the novel lab book systems, which could be adopted across the faculty. The review committee heard about possible plans to include MERLN in a research school to be better in line with the governance structure of the faculty. The review committee questions whether being part of a research school would be the best way forward for the institute since it might be a risk for the visibility created very carefully over the last six years. The review committee would advise to look for a format where the coherence of the institute as well as the very special open and creative bottom-up culture will not be affected.

11. Major recommendations for improvement

- The anticipated growth of the institute is not possible with the current lab space that is available to MERLN. This will become even more apparent with the start of a new bachelor. Possibilities for more space should become clear as soon as possible. The review committee also suggests considering attention for more administrative and technical support to balance the workload for (younger) PIs.
- The review committee recommends the establishment of common guidelines in the MERLN institute on the supervision of PhD students and postdocs (e.g. frequency, content, personalized training plans) and the promotion of exchange of best practices among its three departments, while keeping the freedom the PIs and department heads have in organising their groups. This will help integrity and establishing specific measures to avoid extension of PhD longer than four years.
- Within FHML and Maastricht University, MERLN is currently a relatively isolated institute and the review committee recommends to ensure stable embedding in the local ecosystem and align with the local facilities/ organisational units. This will facilitate sustainable growth of the institute and also benefit two major issues that are currently apparent:
    - Since valorisation is one of the goals of MERLN, aligning expectations and vision between the MERLN and the TTO and Brightlands Maastricht Health Campus regarding the potential value of research findings for patenting as well as valuing the relevance of a (set of) patent(s) for spin-off activities or licensing is necessary. The staff would therefore benefit from better support from the university in translating the findings.
    - The review committee recommends that the MERLN Institute prioritizes alignment of their Academic Track Development System with the UFO profiles and UM Tenure Track policy of the FHML faculty, to avoid unnecessary delays in promotions, increase transparency on career perspectives for young PIs, and ensure retention of talent.
- MERLN aims to develop technologies to be applied in Regenerative Medicine. As a consequence, the research lines seem rather diverse, including continuously exploring new areas. The committee wants to encourage MERLN to ensure cohesion of the overall research portfolio. Whilst this is absolutely valid to spread the technologies and platforms developed in MERLN as widely as possible and curiosity is absolutely essential in an academic environment, scientific quality and translation of the technology to science and clinics require strong links with expert clinicians and other life scientists. The review committee recommends to consider the appointment of clinicians in the institute.
- From a viability perspective, it is advised to define explicitly a long term strategy with tangible goals, with a clear organisational chart, and including financial risk mitigation approaches, in order to ensure sustainable growth and maturation of the MERLN institute. Strategic growth and maturation could, for example, be monitored on an annual basis by installing a scientific advisory board consisting of relevant scientists from academia, the clinic, and industry.

12. Annexes

12.1 Annex 1: Members of the External Review Committee

Prof.dr. Gerjo van Osch, Erasmus MC, Rotterdam, The Netherlands (chair)

Gerjo van Osch is medical biologist and did her PhD research on osteoarthritis in Nijmegen and started working in the field of Tissue Engineering as a postdoc in 1994. She is full professor with a chair at the department of Orthopaedics and Sports Medicine and the department of Otorhinolaryngology at Erasmus MC as well as at the department of Biomechanical Engineering at TU Delft. Her research focusses on cellular aspects of repair processes during degeneration and regeneration of musculoskeletal tissues. She has participated and led several (inter)national research consortia and is currently the chair of the European Chapter of the Tissue Engineering and Regenerative Medicine International Society.

Prof.dr. James Kirkpatrick, Universität Mainz, Germany

C. James Kirkpatrick has a triple doctorate in science and medicine (MD, PhD, DSc) from the Queen's University of Belfast, and from 1993 to 2015 was Professor and Chairman of Pathology at the Johannes Gutenberg University (JGU) in Mainz, Germany, where he is now Emeritus Professor. Previous academic appointments were at the University of Ulm, University of Manchester and the University of Technology (RWTH) in Aachen. His principal research interests are in biomaterials in tissue engineering and regenerative medicine, with special focus on vascularization and nanomedicine. Kirkpatrick is a former President of both the German and the European Society for Biomaterials, and has served on the Council of the European Chapter of TERMIS. He is currently a member of the TERMIS Ethics Committee.

Prof.dr. Gijsje Koenderink, TU Delft, The Netherlands

Gijsje Koenderink leads a research group specialized in cell and tissue biophysics, which is embedded in the Bionanoscience Department and Kavli Institute of Nanoscience at TU Delft. She originally trained as a chemist, did her PhD research in Utrecht working in the field of physical chemistry (2003), and did postdoctoral research at the VU University Amsterdam and Harvard University in the field of biophysics (2004-2006). Between 2006-2019, she worked as a group leader at the AMOLF Institute in Amsterdam, and in 2019 she relocated her group to TU Delft. Her research focuses on fundamental material properties of biological cells and tissues and is closely linked to biomedical applications in the context of regenerative medicine and cancer.

Prof.dr. Liam Grover, University of Birmingham, United Kingdom

Liam M Grover is a Professor of Biomaterials Science and Director of the Healthcare Technologies Institute at the University of Birmingham. His research focusses on the interactions that occur between the materials and biological systems. By developing an understanding of these interactions, he has developed a number of novel technologies that enhance regeneration. He is a serial medical innovator, having filed more than 20 patents that describe the formulation of new bone replacement materials, skin-dressings, eye-drops and anti-viral nasal sprays. He has spun-out two companies (NanuNanu and Healome), and moved four products from concept to the point of clinical trials. He has written >200 peer-reviewed papers and has been involved in raising >£40m of research funding.

Prof.dr. Maria-Pau Ginebra, Universitat Politècnica de Catalunya, Barcelona, Spain

Maria-Pau Ginebra is Professor and Head of the Department of Materials Science and Engineering at the Universitat Politècnica de Catalunya (UPC, Barcelona, Spain) where she leads the Biomaterials, Biomechanics and Tissue Engineering Group, and Associate researcher at the Institute of

Bioengineering of Catalonia (IBEC). Her research lines include the design of new biomaterials for tissue regeneration, with special emphasis in the skeletal system, and the fundamental study of the biological mechanisms that control the interactions of biomaterials with cells and tissues. She explores new strategies of biomaterials fabrication, including injectable foams and 3D printing of implants for regenerative medicine, as well as the design of multifunctional surfaces with bioactive and antimicrobial properties.

Dr. Arnold Boersma, DWI-Leibniz Institute for Interactive Materials, Aachen, Germany

Arnold Boersma is a group leader at the DWI-Leibniz Institute for Interactive Materials, and faculty at the Max Planck School “Matter to Life”. His research focuses on biomolecular engineering and synthetic biology for applications in diagnostics, screening, and fundamental understanding. He obtained his PhD at the University of Groningen under the guidance of profs. Ben Feringa and Gerard Roelfes and did a postdoctoral fellowship at the University of Oxford with Prof. Hagan Bayley. He then returned to the University of Groningen and moved to the DWI-Leibniz Institute in 2018.

Dr. Cristianne Rijcken, Cristal Therapeutics, The Netherlands

Dr. Cristianne Rijcken is the founder of Cristal Therapeutics, and serves as Chief Scientific Officer of the company. Dr. Rijcken’s PhD thesis provided a strong basis for Cristal Therapeutics and she was awarded multiple grants and prizes including the Simon Stevin Gezel Award in 2008 and the Knowledge for Growth Inspiring Young Scientist Award in 2014. She is (co-) author of ~ 45 scientific publications and co-inventor of all patents and patent applications of Cristal Therapeutics. Dr. Rijcken is pharmacist by training and holds a PhD degree in Pharmaceutics from Utrecht University (The Netherlands).

Aref Saberi (PhD candidate), University of Eindhoven, The Netherlands

Aref Saberi is a Biomedical-Engineering PhD candidate at Eindhoven University of Technology, under the supervision of Prof. Carlijn Bouten and Dr. Nicholas Kurniawan. His research focuses on the development of in vitro platforms for the study of human brain development and pathologies. Aref obtained his master's degree from Eindhoven University of Technology. He also has experience as a visiting researcher at the laboratory of Prof. Zhenan Bao at Stanford University, working on stretchable micro-electronics.

Dr. Roelinka Broekhuizen, secretary, The Netherlands

Roelinka Broekhuizen did her PhD in Maastricht at the school NUTRIM. She works as an independent consultant, now working for the Dutch Society of Nutritional Sciences (NAV), SMBWO, Nutritional Science Days and Louis Bolk Institute. She has been hired as an independent Secretary of the review committees of Nutrim/VLAG in 2015, for CAPHRI in 2017, for CARIM in 2019 and now for MERLN.

13.2 Annex 2: criteria of SEP

The main goal of a SEP evaluation is to evaluate a research unit in light of its own aims and strategy

Assessment criteria

Research quality

The quality of the unit's research over the past six-year period is assessed in its international, national or – where appropriate – regional context. The review committee does so by assessing a research unit in light of its own aims and strategy. Central in this assessment are the contributions to the body of scientific knowledge. The review committee reflects on the quality and scientific relevance of the research. Moreover, the academic reputation and leadership within the field is assessed. The committee's assessment is grounded in a narrative argument and supported by evidence of the scientific achievements of the unit in the context of the national or international research field, as appropriate to the specific claims made in the narrative. The protocol explicitly follows the guidelines of the San Francisco Declaration on Research Assessment (DORA)2 adopted by KNAW, VSNU and NWO.

Societal relevance

The societal relevance of the unit's research in terms of impact, public engagement and uptake of the unit's research is assessed in economic, social, cultural, educational or any other terms that may be relevant. Societal impact may often take longer to become apparent. Societal impact that became evident in the past six years may therefore well be due to research done by the unit long before. The review committee reflects on societal relevance by assessing a research unit's accomplishments in light of its own aims and strategy. The review committee also reflects, where applicable, on the teaching-research nexus. The assessment is grounded in a narrative argument that describes the key research findings and their implications, while it also includes evidence for the societal relevance in terms of impact and engagement of the research unit.

Viability

The extent to which the research unit's goals for the coming six-year period remain scientifically and societally relevant is assessed. It is also assessed whether its aims and strategy as well as the foresight of its leadership and its overall management are optimal to attain these goals. Finally, it is assessed whether the plans and resources are adequate to implement this strategy. The review committee also reflects on the viability of the research unit in relation to the expected developments in the field and societal developments as well as on the wider institutional context of the research unit.

The three main assessment criteria 1) research quality, 2) societal relevance and 3) viability are central in the assessment of the research unit. These three criteria include several aspects depending on the aims and strategy of the research unit. Among all relevant aspects, the research unit addresses at least the following four specific aspects: 1) Open Science, 2) PhD Policy and Training, 3) Academic Culture and 4) Human Resources Policy in concert with the main assessment criteria. The review committee should also take these into account.

13.3 Annex 3: programme MERLN review 2021

Day 1 – Wednesday 27/10/2021 (only evening program)

Location: Kruisherenhotel and Chateau Neercanne, Maastricht

Time	Activity
Afternoon	Arrival members External Review Committee in Maastricht
18.00	Departure to restaurant (taxi)
18.30-19.00	Welcome and installation External Review Committee members by Dean of the Faculty of Health, Medicine and Life Sciences (FHML) Board (Prof. Annemie Schols), in presence of MERLN Management Team Committee Members: Prof. Gerjo van Osch *(Chair)* Prof. James Kirkpatrick *(not present)* Prof. Gijsje Koenderink Prof. Liam Grover Prof. Maria-Pau Ginebra Dr Arnold Boersma Dr Cristianne Rijcken Mr Aref Saberi Dr Roelinka Broekhuizen *(Secretary)* Management team MERLN: Prof. Pamela Habibovic *(Scientific Director and Chair of IBE department)* Prof. Lorenzo Moroni *(Vice Director and Chair of CTR department)* Prof. Martijn van Griensven *(Chair of cBITE department)* Prof. Roman Truckenmüller *(Professor at IBE department)* Prof. Clemens van Blitterswijk *(MERLN founder and Scientific Director until 2019)* Dr Sef Janssen *(Managing Director)*
19.00-22.30	Dinner
22.30	Departure to hotel (taxi)

Day 2 – Thursday 28/10/2021

Location: Maastricht University (Universiteitssingel 40/50)

Time	Activity
8.00	Departure to UM (taxi)
8.20-8.45	Welcome at MERLN and tour of MERLN office *(Prof. Pamela Habibovic)*
	Closed morning session
8.45-10.15	External Review Committee discusses working procedures and reporting
	Public morning session
10.15-10.45	Introduction to FHML and MUMC+ *(Dean of FHML: Prof. Annemie Schols)*
10.45-11.15	Introduction to MERLN *(Prof. Pamela Habibovic)*
11.15-11.30	Discussion
11.30-11.45	Coffee break
11.45-12.05	Short introduction to cBITE department

	(Prof. Martijn van Griensven)
12.05-12.25	Short introduction to CTR department *(Prof. Lorenzo Moroni)*
12.25-12.45	Short introduction to IBE department *(Prof. Pamela Habibovic)*
12.45-13.30	Lunch break
	Closed afternoon session
13.30-14.15	Closed session of External Review Committee
	Public afternoon session
14.15-15.00	Site visit to MERLN laboratories Laboratories 3rd floor Laboratories 4th floor Laboratories 5th floor *(Guides: Dr Carlos Mota, Dr Paul Wieringa, Dr Timo Rademakers; Chaperones: Dr Vanessa LaPointe, Dr Dennie Hebels, Denis van Beurden)*
15.15-16.30	Coffee break with poster viewing (one per PI) and meeting with senior staff and PhD students/postdocs *(Senior staff, PhD students/postdocs)*
	Closed afternoon session
16.30-18.00	External Review Committee reflection and preliminary conclusions
18.00	Departure to hotel (taxi)
	Evening program
19.15	Departure to restaurant (on foot or taxi)
19.30-22.30	Dinner *(Management team, assistant and associate professors, and representatives of PhDs, PDs, and support staff)*
22.30	Departure to hotel (on foot or taxi)

Day 3 – Friday 29/10/2021

Location: Maastricht University (Universiteitssingel 40)

Time	**Activity**
8.00	Departure to UM (taxi)
	Public morning session
8.30-10.00	Meeting with PhD coordinator, PhD representative and junior investigators *(Dr Sabine van Rijt, Adrian Seijas Gamardo, PhD students, postdocs) (Dr van Rijt leaves the room at a certain moment upon request by the committee)*
10.00-10.45	Meeting with senior investigators *(Assistant and associate professors)*
10.45-11.00	Coffee break
11.00-11.30	Bachelor and Master programs FHML and FSE *(Dr Sabine van Rijt, Dr Matt Baker, Dr Jurica Bauer, Liline Fermin, Aylin Seedorf)*
11.30-12.15	Open Science, scientific integrity, outreach, workshops and lectures *(Dr Matt Baker, Dr Dennie Hebels, Dr Niloofar Tahmasebi, Anika Schumacher)*
12.15-13.00	Clinical collaboration and research translation: Examples of scientific and societal use *(Prof. Marianne van der Steen, Prof. Jan Cobbenhagen, Prof. Han Brunner, Dr Vanessa LaPointe)*

	Closed afternoon session
13.00-14.00	Closed session of External Review Committee, including lunch
	Public afternoon session
14.00-14.30	Meeting with representatives of FHML Board *(Prof. Jos Prickaerts and Prof. Mirjam Oude Egbrink, page 10)*
14.30-15.00	Meeting with the Scientific Director and Managing Director of MERLN *(Prof. Pamela Habibovic, Dr Sef Janssen)*
	Closed afternoon session
15.00-16.00	Closed session of External Review Committee
	Public afternoon session
16.00	Preliminary conclusions of External Review Committee by the Chair, Prof. Gerjo van Osch End of official program and informal get-together *(Audience: part of MERLN, Prof. Jos Prickaerts and Prof. Mirjam Oude Egbrink)*