

LIFE SCIENCE NORD CLUSTER STRATEGY 2024



IMPRINT

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LIST OF ABBREVIATIONS

LSN Life Science Nord

LSN Management

Life Science Nord Management GmbH/ Cluster Management

GWHH

Gesundheitswirtschaft Hamburg GmbH (Cluster Agency Healthcare Hamburg)

DEAR LADIES AND GENTLEMEN,

Together, we want to shape the future of the worldwide health care system – from Northern Germany! With this newly formulated vision, Cluster Life Science Nord (LSN) will position itself even more actively in the future as a leading Life Science Cluster in Europe, recognised for its excellent companies and scientific institutions, innovation-friendly framework conditions and professional Cluster Management in the field of Life Science. The potential for this is undoubtedly there, as the recent past has shown. Under this motto, and with this vision, LSN plans to act in the next years and to align its activities.

In times of digital transformation and convergence of various technologies, however, new challenges also arise for the key Life Science industry in northern Germany. New aspects, such as artificial intelligence, should be understood as an opportunity rather than a danger and converted into competitive advantages. In order to meet these and other challenges even better in the future, the LSN Cluster has adapted its strategy in a participatory process with the active involvement of its members. This strategy should now be implemented jointly over the next few years. The stakeholders from science and industry are actively supported by politicians. Schleswig-Holstein and Hamburg have been actively involved in the LSN development process for many years through their investments in LSN Management GmbH. This will continue in the future. Life Science Nord eV. will continue to play an equally central role.

This brings together around 250 stakeholders from science, industry and politics with the common goal of successfully leading Hamburg and Schleswig-Holstein into the future as Life Science locations.

LSN does not act alone, but is embedded in an efficient cluster landscape of both federal states. The associated cluster policy represents a stable and long-term framework for successful cluster development. It is important that the clusters act together even more actively in the future. Together, we want to shape the future of the worldwide health care system – from Northern Germany!



Minister Dr. Bernd Buchholz

I d Aurz

The deepening cooperation between LSN and corresponding initiatives of the health economy, such as the Cluster Agency Healthcare Hamburg, which links stakeholders of the Life Sciences more closely with those of the health economy, could have exemplary character.

We are pleased to be able to present the results of the strategy process to you with this brochure and are confident that Life Science Nord will also be able to operate very successfully in the coming years with the implementation of this strategy.



Senator Michael Westhagemann



1. Chairman LSN e.V. Dr. Mathias Kraas

SUMMARY

The LSN Cluster with its approximately 500 companies from the fields of medical technology, biotechnology and pharmaceuticals, universities of applied sciences and other universities, as well as non-university research institutions and clinics, forms an important innovation and economic factor for the two federal states of Hamburg and Schleswig-Holstein. At the same time, LSN has been an important element of the cluster policy of the federal states for years and plays an important role in both regional innovation strategies. Since the strategy process in 2013, LSN has continuously professionalised its range of services in line with the needs of the cluster stakeholders, further promoted targeted cooperation between science and industry and thus made a significant contribution to increasing the added value and innovation capability of the region.

In particular, the focus on infection and hygiene, bone healing and digital health within the framework of innovation funding has made it possible to consistently expand existing and future relevant competencies in the cluster – in the spirit of intelligent specialisation and sustainable profiling as an internationally significant Life Science location. The success in cluster work has since been reflected in the development of the LSN e.V. Since the merger of the two former associations Bay to Bio and AGMT – Arbeitsgemeinschaft Medizintechnik – in 2013, the number of members has grown continuously and qualitatively, always taking into account the balance in the structure of the industry focal points and value-added stages.

In order to also take this positive development into account in the future, it is necessary to put the goals and measures that have been achieved to-date to the test and to realign them. New challenges from technological innovations, market changes, regulatory requirements, or increased competition for talented and qualified specialists lead to changed framework conditions which directly influence the competitiveness and innovation capability of the Life Science sector. On this occasion, from July 2018 to March 2019, a critical inventory analysis was carried out in a multi-stage strategy process with close involvement of the LSN e.V. Executive Board, the LSN Cluster Management Supervisory Board and the cluster stakeholders, new fields of action were defined and concrete goals and measures were derived, taking into account the identified challenges.

The cluster aims to make global health care sustainable through innovative solutions from Hamburg and Schleswig-Holstein and thus be recognised worldwide as a hot spot in the Life Science Sector. The excellent companies and scientific institutions in the region, innovation-friendly framework conditions and professional Cluster Management are key success factors for this.

The following strategic goals have been set in order to achieve this ambitious vision:

- > Strengthening competencies in selected areas to ensure international competitiveness
- > Increasing the output of innovation through new forms of cooperation between science and industry
- > Creating competitive advantages by supporting cluster members in dealing with the upheavals of digitalisation

- > Support in coping with the growing global requirements of the regulatory framework ("Regulatory Affairs")
- > Increasing the competitiveness of the region through a closer integration of Life Science and Health Economy
- > Increase international visibility to strengthen the magnet effect for resettlement, skilled workers and leading innovation stakeholders

To address the central challenges and associated strategic goals directly at a work level, six medium-term operational goals were defined as part of the participatory strategy process. These goals define the actions of LSN Management and LSN e.V. and contribute to achieving the strategic goals over the long term. The operational targets are as follows:

- > Developing and visualising specific skills through key topics
- > Facilitating cross-sectoral innovation through improved infrastructure
- > Facilitating access to knowledge and skills as a key resource
- > Developing innovation and start-up culture
- > Shaping cooperation between business and science to meet demand
- > Making LSN more accessible as a think tank for regional development

LSN Management accompanies all operational goals through concrete measures in close cooperation with relevant partners, both within the cluster and beyond. Existing and proven activities will continue to be implemented. New projects, such as the establishment of a test field infrastructure for the initiation of cross-sectoral innovations, will complement these projects in order to increasingly convert current and future challenges in theLife Science Sector into new innovations and value creation potential.

Due to the increasingly complex and changing framework conditions, LSN Management and LSN e.V. are generally faced with increasingly demanding expectations and tasks that require an interdisciplinary and integrated understanding of Cluster Management and all associated activities. The LSN Cluster Strategy 2024 therefore introduces the four guiding philosophies "Sustainable Cluster Management", "needs-based service spectrum", "intelligent partnering" and "focused branding". which characterise the entire spectrum of LSN's activities.

Finally, continuous success and impact monitoring is crucial for the future success of LSN. It is seen less as a control instrument and more as an active steering instrument for LSN management and the corresponding steering committees. This enables a flexible adaptation of target formulations and associated measures in the event of possible undesirable developments. LSN Management will review the internal action plan and indicator system at regular intervals and in consultation with the Executive Board and the Supervisory Board.

LIFE SCIENCE NORD 2013 – 2018

Within the framework of the last strategy process in 2013, the LSN Cluster realigned itself and set various priorities in order to achieve an increase in added value in the fields of medical technology, pharmaceuticals and biotechnology in the region, an increase in cooperation between industry and science and the sustainable promotion of innovations. The associated objectives were consistently pursued and appropriate measures implemented. LSN has developed continuously over the years through the intensive cooperation of economic, scientific and political stakeholders. Many innovations and successful projects have emerged from the cluster work of recent years.

The development of LSN, which is representative of the success of recent years, is described below using selected examples.

THE ECONOMIC FOOTPRINT OF THE LIFE SCIENCE NORD CLUSTER

The LSN Cluster represents an important industrial sector and a strong research location in the region. The study "The Economic Footprint of the Life Science Nord Cluster" further quantified this fact.¹ The gross value added of the cluster amounted to EUR 4.3 billion in 2016.² 43% of gross value added was generated in the biotech/pharmaceutical segment (incl. wholesale), 31% in the medical technology segment. 8,600 of the total 49,900 employees work in the field of research and development, which proves the research intensity of the industry in the region. Approximately 49,900 employees in the LSN Cluster secure around 13,800 additional jobs with the cluster's predecessors. The reinvestment of their incomes will create a further 12,600 jobs in the overall economy of the region.

The term "economic footprint" refers to the overall economic impact of sectors on the basis of economic indicators such as gross value added or export volume.

²⁾ The complete study can be viewed at https://www.lifesciencenord.de/en/about-us/key-indicators-for-the-cluster/

The figures once again demonstrate the importance of the industry for the region.

Figure 1: Key figures on gross value added of the industrial healthcare sector for the Hamburg and Schleswig-Holstein region (for 2016)



Gross value added of the cluster in 2016



Gross value added / capital in HH and S-H



Additional gross value added since 2014



Ø growth p.a. between 2014 and 2016, price-adjusted

DEVELOPMENT OF THE CLUSTER ORGANISATION

Further development and increasing professionalisation of LSN's Cluster Management was an important field of action for the Strategy 2013–2018. As a result, great importance has been attached in recent years to ensuring that the Cluster Management team has been adequately strengthened in terms of personnel and expertise. Strategic projects for the members could be initiated and companies, research institutions and clinics could be supported according to their needs, which contribute to the profiling of the Hamburg/Schleswig-Holstein area. The personnel capacity in Cluster Management rose from eight full-time equivalents in 2013 to 13.5 in 2018.

Within the context of this professionalisation, Cluster Management successfully met the challenges of European certification for Cluster Management excellence in 2015. As a result of external auditing, LSN was awarded the Gold Label for Excellence in Cluster Management.



This award and the associated re-certification in 2018 had very positive effects both internally and with regard to the members. In a survey of the cluster stakeholders at the end of 2016, LSN Management's work was assessed as clearly positive. This assessment is also reflected in the entry of 21 new members into LSN e.V. in 2017.

Since 2013, LSN has significantly expanded its range of services and is thus in a position to support its members in a more targeted and demand-oriented manner than before. Over the last few years, a solid foundation has been established to successfully manage the future challenges arising from the implementation of the new LSN strategy.

SIMPLIFICATION OF STRUCTURES AND BRAND BUILDING

Based on the founding of LSN e.V., which was founded in 2013 through the merger of Arbeitsgemeinschaft Medizintechnik e.V. (AGMT, Working Community Medical Technology e.V.) and Bay to Bio Förderverein Life Science Nord e.V. based in Lübeck, a clear positioning of the LSN Cluster in the three main areas of biotechnology, medical technology and pharmaceuticals was established. Since then, the Förderverein has functioned as a central organisational and network platform to strengthen these three industries.

In 2015, Norgenta North German Life Science Agency GmbH was renamed Life Science Nord Management GmbH with the aim of being more clearly perceived as an LSN Cluster – and thus also as a Life Science location in Hamburg and Schleswig-Holstein – in a supra-regional context. This represents a decisive step towards the formation of a uniform and internationally visible "Life Science Nord" brand. LSN eV. holds a 20% stake in the Cluster agency LSN Management GmbH and the two states each hold a 40% stake. The Cluster Management links business, research and politics in the north and brings the expertise of universities and research institutions as well as its own close contacts to companies. It organises and participates in working groups and events, offers advice and initiates strategic projects for the development of innovative medicines, medical products and services, establishes international contacts for positioning the location and the stakeholders and offers its own formats for qualification and further training.

The marketing and communications strategy was consistently applied and implemented from 2017, e.g. in a uniform appearance for publications and the internet presence. The latter was further developed and professionalised accordingly. For the main projects HIHEAL, Northopedics and QualiFIT own brands were developed and integrated into the digital and printed communication. The LSN Magazine has become one of several prestigious marketing tools.

PRIORITY FORMATION FOR INNOVATION PROMOTION

From the very beginning, the promotion of innovation and the associated networking of business and science have been a major goal of LSN. LSN has therefore developed a wide range of services in the field of innovation promotion over time. Today, LSN acts on the one hand as a competent contact for the cluster stakeholders in innovation-relevant questions. Due to extensive knowledge of the regional industry and research landscape as well as diverse contacts, LSN is in a position to provide demand-oriented support.

Therefore, it is not surprising that the Cluster Management brings together consortium partners for research projects in a targeted manner or accompanies the cluster stakeholders during the application process. In 2017, the total project volume of these applications amounted to 15 million euros.

Over the past few years, Cluster Management has succeeded in initiating concrete projects for and with LSN's cluster stakeholders in order to successfully advance the approach of thematic focus formation. The following focal points were identified with the involvement of the LSN e.V. Executive Board:

> Infection and hygiene

- > Bone healing
- > Digital health

Projects that focus on one of the three focal points enable LSN to devote more attention to selected innovation-relevant issues.

The specialised projects aim to deal with individual priority topics in greater depth with cluster stakeholders.

> The project Hygiene, Infection & Health (HIHeal) aims to establish a cross-cluster network in the fields of hygiene, infection & health along a common value chain between the clusters of Healthcare Hamburg and LSN. Like the eHealth project (see below), it is being implemented as a "cluster bridge project" in close cooperation with the Cluster Agency Healthcare Hamburg. HIHeal networks Stakeholders in this field, including companies, scientific institutions, clinics and cost units in Hamburg. The spectrum of topics includes the development of strategies and technologies for the prevention, diagnosis and therapy of infectious diseases. The spectrum of topics includes the development of strategies and technologies for the prevention, diagnosis and therapy of infectious diseases.



> The eHealth project, also initiated as part of the cluster bridge approach (see above), aims to bundle the synergies with the focus on digital health. In addition to the implementation of various event formats (eHealth Lounges, eHealth Day, expert workshops, etc.) and the associated establishment of a network, innovation projects are initiated and start-ups promoted. > Another focal point was identified with the "Bone Healing/Northopedics" competence network and promoted on a project-related basis. Musculoskeletal diseases play a major role in the state of health of society. Their importance will continue to rise as a result of demographic change. The Northopedics project will create a competence network with clinicians, basic researchers from various disciplines and industrial companies that will identify and address key medical issues.



- > The Baltic Fracture Competence Centre (BFCC) project strengthens LSN's position in bone healing with a particular focus on fracture management. BFCC has developed and implemented a transnational fracture registry platform of five hospitals from Estonia, Germany, Lithuania, Poland and Sweden, which enables a comparison of process and outcome quality between institutions and countries. This transnational research and innovation infrastructure will promote evidence-based identification of clinical best practices and innovation needs.
- > The Bonebank project aims to establish and implement a German-Danish biobank for bone marrow stem cells, mainly through the development of methods for obtaining bone marrow stem cells in clinical fracture treatment as part of routine operations.

Furthermore, LSN and selected stakeholders were and are involved in different network partnerships on various topics, which primarily pursue the goal of improving the national and international cooperation network of LSN. Relevant projects include InnoCan (test centre for new innovative solutions for the treatment of cancer), HealthCAT (development of a robot prototype for use in care wards), CellTom (development of medical imaging methods for rapid tumour recognition) or Antimik (network antimicrobial surfaces and hygienic coatings).



QUALIFICATION AND SECURING OF SPECIALISTS

The LSN Strategy 2013 – 2018 actively pursued the topic of qualification. Since then, a number of activities have been successfully implemented and continued, such as student conferences, a cooperation with T5 Interface (T5 job fair organiser) or projects such as QualiFIT or QualiCS, in the framework of which selected project partners are given space for the industry-specific expansion of needs-based further training opportunities.

Since 2017, LSN ACADEMY has been a mainly online-based continuing education and qualification program aimed explicitly at specialists and managers in the Life Science Sector. The self-learning courses were designed by LSN Management in cooperation with oncampus GmbH, the University of Applied Sciences Lübeck and the Fraunhofer Institute for Marine Biotechnology and Cell Technology as part of the QualiFIT project funded by ESF and state funds. Members of the LSN e.V. have the opportunity to take advantage of low-cost and discounted offers in the fields of "Management" and "Research & Technology" and to continue their education in addition to their profession.

STRENGTHENING MEMBERSHIP STRUCTURE AND INTEGRATION

The LSN Cluster has grown continuously over the years. Out of the approximately 500 companies in the region, around 250 stakeholders from science and industry are integrated in the cluster as members of LSN e.V. Many value chains in the Life Science Sector are covered completely or as far as possible. Special emphasis was placed on qualitative member growth.

Members of LSN e.V. can use various partner programs and thus different levels of exclusive offers, graded according to the precious metals platinum, gold and silver. In this way, offers associated with membership in LSN e.V. can be adapted to the needs of the company. This, as well as the various working groups established in the past, has led to many companies not only being members of the LSN, but also actively participating in the cluster work. The entire cluster with all its stakeholders benefits from this.



THE EMBEDDING OF LIFE SCIENCE NORD INTO THE REGIONAL AND NATIONAL INNOVATION SYSTEM

The LSN Cluster and its stakeholders represent an important innovation and economic factor for the Hamburg and Schleswig-Holstein region in the fields of medical technology, biotechnology and pharmaceuticals. The cluster represents approx. 500 companies, 50,000 jobs, 5 universities and 4 universities of applied sciences, more than 12 extra-university research facilities and 2 university clinics.

At the same time, LSN has been an important element of the cluster policy of the federal states for years and plays an important role in both regional innovation strategies. The Supervisory Board of LSN is made up of high-ranking political representatives, which also ensures a close exchange of specialist political views. A number of projects implemented by LSN's Cluster Management are funded by one or both of the federal states at the same time, as LSN's cluster approach is expected to have the greatest impact and effects on the cluster stakeholders involved.

Some of these projects are carried out together with the Cluster Gesundheitswirtschaft Hamburg GmbH (Cluster Agency Healthcare Hamburg) due to their professional proximity. Overall, the exchange with this cluster initiative and many others in the region is close and continuous.



For example, there are links to the cluster initiatives of Hamburg Aviation, Maritime Cluster Northern Germany or foodRegio, in regards to the topic "Innovative Production Technologies". In the context of the "digital transformation", thematic cooperation with the cluster initiatives Hamburg Kreativ Gesellschaft or Digitale Wirtschaft Schleswig-Holstein can be expected to increase in the future. This shows that LSN is an important stakeholder in the North German innovation system due to its interdisciplinarity, industrial and research-specific strength as well as thematic breadth. In line with the innovation strategies of both states the cluster initiatives also have the important function of intensifying research activities between science and industry in the strategic fields of specialisation. The aim is to secure the long-term competitiveness of the science and business locations of both states, and above all to sustainably secure the efficiency of the local small and medium-sized enterprises.³

LIFE SCIENCE NORD AS PART OF THE LIFE SCIENCE CLUSTER LANDSCAPE IN GERMANY

In addition to the regional embedding of the LSN Cluster, the location within the national innovation system or the Life Science industry must also be considered. According to the information on the Cluster Platform Germany, the central information portal on cluster-related topics of the Federal Ministry of Economics and Energy and the Federal Ministry of Education and Research, there is a large number of cluster initiatives with thematic references to the fields of Life Sciences, biotechnology, medical technology and pharmaceuticals. These are characterised by different levels of development and performance. Some of the cluster initiatives are also research and business-related hotspots such as LSN. Overall, it can be said that the LSN Cluster in Germany is one of several leading clusters in terms of membership and Cluster Management excellence.

3) Cf. see: Free and Hanseatic City of Hamburg. Authority for Economic Affairs, Transport and Innovation (2014); see also: Ministry of Economics, Labour, Transport and Technology of the State of Schleswig-Holstein (2013; 2014) In addition to the increased international focus, cross-regional cooperation within Germany will also gain in importance in the future. For this reason, it will be important to follow the developments of relevant cluster initiatives and their cluster stakeholders in order to initiate research and economic cooperations with stakeholders who possess leading market and technology competence.

The following map shows selected Life Science Cluster initiatives from Germany. An overview with short portraits is attached to the strategy document. The representation is based exclusively on publicly freely available information.⁴



Figure 2: Regional location of cluster initiatives from Germany in the area of Life Science and Biotechnology⁵ (own research)

 4) Note: Only cluster initiatives that are already well established and have a higher level of performance or excellence are presented as examples.
 5) Note: The regional cluster initiatives are members of the "go-cluster" program of the Federal Ministry of Economics and Energy. Source: Cluster platform Germany. www.clusterplattform.de (last accessed on 08.01.2019)

LIFE SCIENCE NORD AS PART OF THE LIFE SCIENCE RESEARCH AGENDA IN GERMANY

The major societal challenges of the 21st century include, for example change, demographic development, scarcity of resources and energy supply, access to information and mobility, and above all, all aspects of health such as the worldwide fight against diseases (including infectious diseases, autoimmune and oncological diseases, social diseases \[civilisation diseases, deficiency diseases] or degenerative diseases) as well as comprehensive health care. Due to the importance of the health challenge, this issue has a high priority and is included in all policy agendas at state, federal and EU level. Due to the fact that LSN is positioned as part of the social challenge "health", there is a high potential for the LSN Cluster and its stakeholders to make a significant contribution here.

In addition to the two state-specific innovation strategies⁶, in which the Life Sciences are each described as a specialisation or emerging, the "High-Tech Strategy 2025: Minds. Competencies. Innovations" and the "Strategy on Artificial Intelligence" are of great importance.⁷ Above all, the new "High-Tech Strategy 2025" in the chapter "Health and care: For an active and self-determined life" describes the core elements of the German research agenda up to the year 2025, which will then be implemented in corresponding funding programs. New research and innovation policy initiatives, which in future will to a large extent offer points of contact for the themes of LSN, are in particular the new "Health Research Framework Program", which will define the strategic direction of funding in this area (from 2019), and the "Digital Health Innovations Roadmap", in order to optimise the cooperation of all those responsible from the development to the implementation of innovative eHealth solutions (from 2019). In these research and innovation policy initiatives, there will be various funding opportunities until 2025 to acquire research projects for LSN's cluster stakeholders.

Due to the new strategic field of action "Digital Transformation" (see chapter 5.2), the "Strategy Artificial Intelligence" of the Federal Government will be relevant for Cluster Management and the cluster stakeholders of LSN in order to open up the ability to use AI applications for the entire bandwidth of the German economy.⁸ Within the framework of the "Platform for Artificial Intelligence"⁹ the "AG 6: Health, Medical Technology, Nursing" is currently working on the possibilities offered by AI applications for prevention, diagnosis and therapy in medicine as well as in nursing and rehabilitation.

At the EU level, "Horizon 2020", the European Commission's funding program for research and innovation, will continue to offer funding until 2020 with Part III "Social Challenges" | 1. Health, demographic change and well-being", references to LSN in terms of content.

7) Cf. see: The Federal Government (2018a) and The Federal Government (2018b)

8) Cf. see: The Federal Government (2018a)

⁶⁾ Cf. see: Free and Hanseatic City of Hamburg. Ministry of Economics, Transport and Innovation (2014) and Ministry of Economics, Labour, Transport and Technology of the State of Schleswig-Holstein (2013, 2014)

⁹⁾ Cf. see: Platform for Artificial Intelligence. Further information: www.plattform-lernende-systeme.de (last checked 08.01.2019)

METHODICAL APPROACH AND STRATEGY PROCESS

The eight-month participatory process (July 2018 to February 2019) to update the strategy of the LSN Cluster was divided into several steps. The Cluster Management, LSN e.V., the Free and Hanseatic City of Hamburg, Schleswig-Holstein and the cluster stakeholders (companies, universities and research institutions, clinics) were all involved in this process, and the previous strategy content was put to the test and further developed. Figure 3 illustrates the main elements of the process that led to the revision of the LSN Cluster Strategy by 2024 and the associated implementation plan.

Figure 3: Methodical approach and strategy process



Based on an initial existential survey (WP 1) an internal kick-off event (WP 2) was carried out with the participation of the Cluster Management, representatives of the LSN e.V. as well as the Free and Hanseatic City of Hamburg and the Federal State of Schleswig-Holstein. In particular, the central expectations with regard to the content, methodology and organisational design of the strategy process were discussed and previous successes and further development potential were determined.

This was followed by an external external launch event (AP2), at which LSN cluster stakeholders and interested industry representatives had the opportunity to inform themselves about the process design and to jointly participate in the content orientation of six thematically oriented, strategic fields of action (see Figure 4), which were jointly formulated by the Cluster Management and its shareholders in the run-up to strategy development.

The results achieved served as the basis for the implementation of six workshops on the strategic fields of action (WP 3), which were dealt with in depth with the involvement of the cluster stakeholders, i.e. specified and further developed with regard to challenges, operational goals and measures. In addition, possibilities for ensuring sustainable Cluster Management in the future were discussed at a seventh internal workshop.



The results of all action field workshops were finally analysed and evaluated in order to design the essential cornerstones of the updated strategy. In the strategy workshop (AP 4), in which the Cluster Management as well as representatives of the LSN e.V. and the two states participated, the essential elements were discussed, specified and supplemented together. This laid the foundation for the revision of the LSN Cluster Strategy. In close exchange with the Cluster Management and taking into account the feedback of the workshop participants, the LSN Cluster Strategy 2024 was finalised (AP 5) and supplemented by an internal implementation and action plan. The conclusion of the strategy process is marked by the presentation of the new Cluster Strategy to the supervisory board of LSN Management GmbH and the board of LSN e.V. as well as the subsequent approval by both bodies.

FUTURE CHALLENGES IN THE LIFE SCIENCE INDUSTRY

The operational goals and proposed measures developed within the framework of the field of action workshops were always derived from the key future challenges in the Life Science Sector formulated at the beginning and expressed by the participating cluster stakeholders. These relate both to technological developments, market changes, regulatory requirements and aspects of the recruitment and development of skilled workers, supplemented by those which relate more to the structural framework conditions in the region.

The central challenges, which justify the strategic and operational goals of the LSN Cluster Strategy 2024 as core elements, are summarised here:

> The changed regulatory framework represents one of the most significant challenges for the industry now and in the future.

The changes in the regulatory framework ("Regulatory Affairs") lead on the one hand to a high degree of uncertainty with regard to regulations and their interpretation, and on the other hand to increased costs that cannot be passed on to the market. Increased regulatory requirements also mean that it is necessary to provide capacities for the preparation of clinical studies.

> There is no access to important users or customer groups, especially from the healthcare industry.

New strategic partnerships must be formed in order to reduce the distance to users. The issue of reimbursability is becoming increasingly important, both in the field of medical devices and in drug approval. In addition, the testing and usability of medical devices in a practical environment are becoming more and more important. It is therefore important to establish proximity to clinicians, patient associations and other stakeholders in the healthcare industry.

> Increased competence development in selected subject areas is necessary in order to remain internationally visible and thus competitive.

The technological competence portfolio of LSN is not yet sufficiently visible on a supra-regional level. In the context of internationalisation, however, the supra-regional visibility of the cluster, its stakeholders and a high reputation of the location play an important role for future competitiveness in the Life Science Sector.

> Digitalisation will be a permanent topic that must be integrated and understood in a practical way for SMEs.

New digital technologies and corresponding business models in health care unfold the greatest possible added value, especially when they are integrated into holistic care concepts. However, many ideas and concepts are realised as isolated solutions. In the future, it will be necessary to look at these as a whole, integrate them and make them more visible within the cluster in order to achieve innovations with a lasting effect.

Furthermore, regulatory frameworks are increasingly playing a crucial role in the development and delivery of digital solutions. Questions of data protection and information sovereignty must be clarified. These aspects will also be ground-breaking for companies and their future business models. It will not only be a question of adding data-based additional services to one's own products. The creation of smart services in platform-based business models will also be decisive for success in the Life Science Sector.

> The framework conditions for start-ups in the Life Science Sector are not yet optimal.

Initial support activities of LSN Management could not be sufficiently perceived by cluster stakeholders and people interested in founding a company in the Life Science Sector.

In addition, many start-up offers in the cluster region have so far been open to different industries and technologies, i.e. LSN's expertise in the field of Life Sciences has not yet been sufficiently taken into account when assessing start-up ideas and concepts.

In order to achieve a sustainable value-adding effect, a complete financial viability of (spin-off) start-ups up to the scaling phase is also decisive for a successful roll-out.

> The lack of skilled workers becomes a competitive disadvantage.

LSN member companies are finding it increasingly difficult to fill their open positions with talented professionals. In addition to attractive career prospects, flexible working time models (keyword: work–life balance) and an inspiring, collaborative working environment are increasingly becoming success factors in recruiting and employee retention.

The increase of motivation and creativity in the future will also be influenced more and more by the use of interactive technologies such as virtual reality or artificial intelligence in the form of collaborative robots (cobots).

For LSN, these aspects will be decisive in the context of talent marketing in order to be perceived and sought as an attractive career location in the Life Science Sector.

> Framework conditions for innovative production technologies are deteriorating.

Production technology often plays an underestimated role in the Life Science Sector. At the same time, this is often of decisive importance, e.g. in medical technology. Overall, it must be noted that the regional framework conditions for production technology have recently become less attractive from the point of view of the member companies. In the context of regional development, production technology as an important location factor for the future was not given any pronounced relevance either. This increasing competitive disadvantage must be counteracted with appropriate measures in the LSN Cluster.

LIFE SCIENCE NORD CLUSTER STRATEGY 2024

As part of the strategy process, a number of strategic and operational goals were formulated, to the achievement of which the implementation of the LSN strategy by 2024 should make an important contribution. The strategy thus formulates the framework for the actions and activities of the Cluster Management and the association in the coming years. The strategic goals have a long-term character and are oriented above all to the current global trends in the industry. In turn, operational goals are subordinated to the strategic goal level, which determine the spectrum of measures in the LSN Cluster and thus the operational work of the Cluster Management. These rather medium-term goals are the direct result of the action field workshops conducted and directly address the various challenges identified by the cluster stakeholders. At the same time, they are designed to make an effective contribution to achieving the strategic objectives.

In developing the strategy, care was also taken to ensure that it was in line with the regional innovation strategies of the two federal states. Since the LSN Cluster is to be seen as an instrument for the development of the Life Science Region, the strategic goals of the cluster must be compatible with those of the two regional innovation strategies.

Figure 5 illustrates the schematic structure of the strategy system and the associated target system. The individual levels and their relationships are described and explained in more detail in the following chapters.

Figure 5: Levels of LSN Cluster Strategy 2024



LSN VISION

Strategic goals

- Strengthening competencies in selected areas to ensure international competitiveness
- Increasing the innovation output through new forms of cooperation between science and industry
- Creation of competitive divides by supporting the cluster members in dealing with the upheavals of digitalisation
- > Support in coping with the growing global requirements of the regulatory framework ("Regulatory Affairs")
- Increasing the competitiveness of the region through a closer integration of Life Science and Health Economy
- Increasing international visibility to strengthen the magnet effect for resettlement, skilled workers and leading innovation stakeholders

Operational goals

- // Expanding competencies and making them visible by focusing on specific topics
- // Facilitate cross-sectoral innovation
 through improved infrastructure
- // Facilitate access to knowledge and skills as a key resource
- // Developing a culture of innovation
 and entrepreneurship
- // Shaping cooperation between business and science according to need
- // Making LSN more usable as a think tank for regional development

Actions

At the same time, the complete coverage of all stages of the value chain – from the idea of a product or process to marketing – remains an elementary component of the Cluster Strategy. A continued consistent focus on specific topics in the fields of medical technology, biotechnology and pharmaceuticals should further sharpen LSN's special competencies and thereby achieve a clearer profile and higher visibility beyond the region. This approach is listed as a separate operational objective in the 2024 Cluster Strategy.

5.1 VISION

The actions of LSN Management, LSN e.V. and its stakeholders are primarily aimed at jointly generating new solutions that continuously improve the health care of the people and ensure the long-term competitiveness of the region. The further development of LSN and the changing framework conditions make it necessary to adapt and reformulate the earlier vision:

Together, we want to shape the future of the worldwide health care system – from Northern Germany!

LSN is establishing itself as a leading Life Science cluster in Europe, where innovative solutions to improve global healthcare are taking place. Through its excellent companies and scientific institutions, the innovation-friendly framework conditions and its professional Cluster Management, it is recognised worldwide as a hot spot in the field of Life Science.



5.2 STRATEGIC GOALS

In order to achieve the ambitious vision of LSN in the long term, it is necessary to address appropriate strategic goals which also respond directly to the particular challenges of the LSN Cluster and the industry. These are both a reaction to the development of LSN in recent years and an answer to the changing framework conditions. Also in the future, LSN will use the strength of the very broadly based competences of business and science to cover the entire spectrum of the value chain. This will continue to require a structured approach by LSN in the periodic identification of new technological and market-relevant trends with the participation of the relevant cluster stakeholders. Even though the strategic goals will most likely remain relevant until 2024 due to their long-term character, it can be assumed that the range of measures and services offered by LSN will continue to evolve in order to be able to offer professional support in line with the needs of the stakeholders in the future as well.

Six strategic goals were identified within the framework of the strategy process, which contribute to the fulfilment of the vision both individually and in their totality. These are not isolated, but are of equal weight and closely interlocked.

1. STRENGTHENING COMPETENCIES IN SELECTED AREAS TO ENSURE INTER-NATIONAL COMPETITIVENESS

LSN covers a comparatively broad spectrum of biotechnology, pharmaceutical and medical technology industries. The strategic approach of the past, in addition to broad competence in selected areas such as bone healing or hygiene, to build up and expand in-depth competence with selected cluster stakeholders through selected projects, has led to initial positive results. In the future, this will have to be transferred from project status to concrete competitive advantages. Therefore, this approach will be pursued further. On the one hand, this means that the results of the current projects are appropriately exploited in order to ensure the

development of competence among the stakeholders involved and thus to transform them into competitive advantages. On the other hand, this means identifying new focal topics and dealing with them in depth in the LSN Cluster. This should take place in a consensual, participatory process.

2. INCREASING THE OUTPUT OF INNOVATION THROUGH NEW FORMS OF COOPERATION BETWEEN SCIENCE AND INDUSTRY

Digital and industrial transformation and increasing technological convergence, but also changing social and cultural conditions, are leading to a change in the way innovations are created. These are becoming increasingly interdisciplinary and cross-sectoral. However, this also makes new forms of cooperation between science and industry necessary. The classic transfer of technology from research to industry will change fundamentally. Some scientific stakeholders will increasingly have to act as "problem solvers" for companies. The increased innovation output must therefore be the focus of cooperation. In test fields to be established, i.e. openly accessible but spatially limited areas with research infrastructure (see also Operational Objective 2), both groups of stakeholders will develop and test prototypical solutions for real practical suitability. All this necessitates new forms of cooperation between science, hospitals and industry from which both sides benefit. Above all, however, such cooperation leads to an increase in innovation output for the benefit of patients.

3. CREATING COMPETITIVE ADVANTAGES BY SUPPORTING CLUSTER MEMBERS IN DEALING WITH THE UPHEAVALS OF DIGITALISATION

Digital transformation has long since found its way into the industries relevant to the LSN Cluster. The strategy process has not only shown that many companies are already prepared for this and are dealing with the topic, but also that partial aspects such as artificial intelligence, big data analytics or digital business models with smart services are already being actively dealt with in the cluster. Start-ups, medium-sized and large companies are already successfully working together with research stakeholders and clinics from the cluster and Northern Germany to develop innovative solutions for digitalisation and in the field of artificial intelligence.

This position must not only be expanded, but also translated into concrete competitive advantages for the cluster stakeholders. Therefore, this strategic goal is to transform the challenge of digital transformation into concrete competitive advantages for local stakeholders.

4. SUPPORT IN COPING WITH THE GROWING GLOBAL REQUIREMENTS OF THE REGULATORY FRAMEWORK ("REGULATORY AFFAIRS")

The regulatory framework for medical devices and in vitro diagnostic medical devices has undergone profound changes in recent years, as many of the relevant laws and standards have been revised and the changes take effect almost simultaneously. These include the new regulations of the quality management system (ISO 13485:2016), the European Union Medical Device Regulation (MDR, EU 2017/745), the European Union In Vitro Diagnostic Medical Devices Directive (IVDR, EU 2017/746) and the Medical Device Single Audit Program (MDSAP). In addition, there are other international challenges such as Brexit or harmonisation efforts in Asia (Asian Harmonisation Working Party, AHWP) or America (Pan American Health Organisation, PAHO).

The changes pose major challenges to many stakeholders and have a direct impact on innovation activity. The innovations, combined with the right strategy, may also offer opportunities and competitive advantages. Therefore, successfully addressing the global requirements of regulatory affairs and how best to deal with these conditions is critical to the future work of the LSN Cluster.

5. INCREASING THE COMPETITIVENESS OF THE REGION THROUGH CLOSER INTEGRATION OF LIFE SCIENCE AND HEALTH ECONOMY

The possibilities offered by digital technologies, even more tailored care for individual patients, and the need for cost efficiency mean that the Life Sciences and the healthcare industry are growing closer together. In the future, product innovations in the field of medical technology can hardly be developed without sufficient proximity to the patient or the application market. New requirements from the healthcare industry directly influence developments in classical medical technology. The eHealth sector, for example, addresses both sectors, and classic boundaries are disappearing. This strategic goal follows one of the main global trends, which can only be achieved in close cooperation with the relevant partners in the region, above all Cluster Agency Healthcare Hamburg and the corresponding stakeholders in Schleswig-Holstein. Here, LSN sees iteself as an important transformational element to advance this interlocking of the existing partner structures for the benefit of the member companies, but also of the people in the region, and thus to come closer to the vision of sustainable health care.

6. INCREASING INTERNATIONAL VISIBILITY TO STRENGTHEN THE MAGNET EFFECT FOR RESETTLEMENT, SKILLED WORKERS AND LEADING INNOVA-TION STAKEHOLDERS

In an increasingly globalised world, which leads to intensified international competition for brilliant minds, innovative companies, excellent research and business environments and attractive framework conditions, the international visibility of Hamburg and Schleswig-Holstein as Life Science locations playing an ever-more important role. LSN competes with excellent Life Science locations both in Germany and abroad. The strategic goal of increasing the international visibility of the Cluster, the cluster stakeholders and the entire Life Science Region is to have a long-term magnetic effect for specialists, researchers and companies of all sizes and thus lead to a concrete competitive advantage for the region. This is to be achieved through a variety of measures in various fields of action.

5.3 OPERATIVE OBJECTIVES AND PLANNED MEASURES

As shown in Figure 6, the Cluster Strategy comprises six different operational goals which, from the point of view of the cluster stakeholders and Cluster Management, concretely identify the central challenges and associated strategic goals. Accordingly, the successful achievement of operational goals contributes above all to the achievement of strategic goals. While the strategic goals have a more long-term character, this is to be regarded as medium-term in the case of the operational goals. The realisation of the operational goals is to be ensured by the concrete spectrum of measures and activities of LSN Management and the association. The measures identified by all the stakeholders involved during the strategy process have therefore been assigned to the respective operational objectives and supplemented by others.

Figure 6: Operational objectives of the LSN Cluster Strategy 2024



OPERATIONAL GOAL 1

EXPAND AND ALSO MAKE VISIBLE SPECIFIC COMPETENCIES BY FOCUSING ON SPECIFIC TOPICS

In the future, LSN will continue to focus on selected technological or indication-specific topics in medical technology, biotechnology and the pharmaceutical industry. Existing but not yet sufficiently visible competencies need to be addressed more clearly, expanded and communicated via projects.

At the same time, relevant new thematic focuses are identified with the cluster stakeholders and promoted as actively as possible by LSN in project form. A close relationship to the test fields or explorative projects to be established should be established where appropriate.

In times of digital transformation and artificial intelligence, these new thematic focuses will also have a corresponding relation to this. Ultimately, an intelligent thematic specialisation in certain thematic focal points serves to create a clear profile of LSN, thereby strengthening supra-regional visibility.

PLANNED MEASURES

> Situation analysis of visibility issues

To begin with, LSN will take stock of the current focus areas of bone healing and hygiene together with the players involved, and will develop measures to stabilise these topics according to the respective project phases. The aim here is to ensure that the project results are transferred into industrial practice. Under the leadership of the GWHH, the topic of eHealth will continue to play a role in cooperative measures in the future.

The measure will be implemented in the short term and will be pursued in the long term.

> Road-mapping process to identify new key issues

The strategy process has made it clear that there is a high level of interest on the part of the cluster stakeholders in participating in new priority topics. This can be both the strengthening of a topic that has already been dealt with by a large number of stakeholders or the conscious development of a new and strategically highly relevant topic area. A joint roadmap process, in which future scenarios and missions are drawn up, is the ideal way of converting the various particular interests with regard to future trends and needs for action into future-oriented focal themes.

Implementation of the measure will begin in the upcoming term.

> Development and implementation of competence enhancement measures

After selecting and naming a focal topic, measures are taken to develop and implement the expansion of competencies. In the first step, this can also mean that the Cluster Management must develop additional resources for the establishment of a priority topic through project proposals.

- > The measure will be implemented in the medium-to-long term.
- > Measures to position and visualise the competences in the relevant thematic focal points In addition to the professional treatment of the current and future focal topics, it is also necessary to become visible in these nationally and internationally. The decisive factor here is to implement a marketing strategy with campaigns, formats and other instruments as part of an integrative process in order to position competencies nationwide and thus strengthen the attractiveness of the cluster as a location for companies, startups and specialists. The following concrete measures can be taken:
- > Writing a position paper around the relevant key topics
- > Integration of testimonials
- > Topic-focused public relations online and offline
- > Further development of the existing strategic partnerships abroad against the background of the targeted development of competencies in selected areas of focus

The measure will be implemented in the medium term.

FACILITATE CROSS-SECTORAL INNOVATION THROUGH IMPROVED INFRASTRUCTURE

Together with GWHH, LSN sees itself as a leading network for the generation of innovations in the Life Science Sector. At the same time, the generation of innovations (products, technologies, processes, services) poses new challenges to all participants due to the increasing interdisciplinarity or the digital transformation. Innovations will become more complex in the future and will emerge differently than in the past.

This operational objective is to be achieved primarily through two new approaches: the establishment and operation of openly accessible test fields and exploratory projects in the non-regulated area, which will be implemented in protected areas. In both cases, prototypical products and processes can be tested with regard to their practical applicability without having to comply with all the rules and guidelines applicable to industrial use from the outset. On the other hand, it is necessary to attract stakeholders outside the traditional Life Science Sector who have important functions and competencies for future cross-sectoral innovations. In particular, cooperation with the Cluster and corresponding partners in Schleswig-Holstein will play a major role here. Cross-sectoral cooperation should also take place in other relevant subject areas (e.g. nutrition, nano/material, IT) in order to create

OPERATIONAL GOAL 2

ideal framework conditions for cooperation between industry and science. It is important here that these stakeholders work together on concrete problems using the improved innovation infrastructure and are thus better interlinked.

Thus, ideal framework conditions can be created for cross-sectoral cooperation between industry and science. Test fields can be understood as real laboratories, innovation labs, or virtual innovation campuses. Test fields and explorative projects should also have a strong connection to digitalisation and increase the international visibility of LSN.

PLANNED MEASURES

In the past, LSN's Cluster Management has already started to address the topic of "cross-sectoral innovation" with the cluster stakeholders in its day-to-day work. Various event formats and projects (e.g. HIHeal) were successfully implemented. This approach is to be continued, but at the same time also strategically expanded. The focus here is on activities that improve framework conditions and, above all, create suitable test fields.

The following measures will be developed and implemented to achieve the objectives:

> Identification and acquisition of new key stakeholders

The increasing interdisciplinarity and the cross-sectoral character require closer access by stakeholders outside the classical Life Science Sector. This is particularly important for the successful implementation of the test field approach. LSN, in coordination and cooperation with relevant partners – in particular the GWHH – will develop a short list of key players that are of particular relevance for integration into cross-sectoral innovations. These are then addressed and won over for participation.

Short lists will be created in the short term. The coordination with relevant partners, identification and selection of key Stakeholders, as well as the approach and follow-up will begin in the upcoming term.

> A Task Force for "Test Field Infrastructure"

Test fields will play an important role in the future as an important instrument of a suitable infrastructure for the development of interdisciplinary and cross-sectoral innovations – not only for the cluster stakeholders, but also for an international magnetic effect of the region that attracts external Stakeholders who demand this infrastructure. Therefore LSN will advance this topic strategically and in close coordination with interested cluster stakeholders on the one hand, but also together with the GWHH as a relevant Cluster partner. To this end, a Task Force should be established, which, among other things, would be responsible for

- » conducting a best-practice analysis of "Life Science Test Fields", which will produce a situation analysis of the current international status quo,
- » developing a concept for "LSN Test Fields" and formulating the contents, goals, contributions of the participants, management, etc.,
- » Identifying relevant partners not only from LSN, but also key Stakeholders from the region who should be actively involved in the Test Field approach,
- » Exploring financing possibilities or acquiring financial resources,
- » Acquiring supra-regional Stakeholders with the aim of winning them over for participation in Test Field activities or explorative projects.

The Task Force's structure and related activities must be incorporated into an integrated marketing strategy in the form of a campaign. The results of the Task Force will be communicated to the public throughout this process

The Task Force will be set up in the short term.

> Design and acquisition of test fields and explorative projects

Explorative projects pursue a similar objective to test fields, but focus less on establishing long-term infrastructures and more on temporary problem-solving. The focus here is on cross-sectoral applications in the non-regulated area. LSN will initiate ideas for test fields and/or explorative projects in close coordination with the cluster stakeholders as well as the GWHH and equivalent partners from Schleswig-Holstein and will try to secure financing.

Test Fields or exploratory projects will be initiated in the long term.

ACCESS TO KNOWLEDGE AND FACILITATE SKILLED WORKERS AS A KEY RESOURCE

LSN supports its members in accessing knowledge and securing skilled workers. Existing instruments, such as the job service "LSN JOBS" job exchange as an onlinebased recruiting tool, need to be developed further in a meaningful and needs-based manner. Furthermore, university and continuing education as well as research in the Life Science context are to be addressed. The aim is to impart not only scientific and technical knowledge but also methodological, social and societal skills. Learning and working in the digital age are of high relevance.

LSN primarily organises solutions and makes optimal use of the competencies both within and outside the cluster through intelligent partnering. The mix of our own and external services ensures a professional, flexible range of services tailored to the needs of our members.

Cross-cutting issues are also to be promoted with the help of cross-sectoral cooperation.

OPERATIONAL GOAL 3

PLANNED MEASURES

Existing face-to-face events and working groups will be continued and the requirements will be adjusted accordingly. These are not listed separately here.

This operational target was already part of the existing strategy, but is to be expanded further in the future with the following measures:

> LSN ACADEMY

The LSN ACADEMY approach will be further developed. In addition to eLearning options, blended learning formats are increasingly being offered in which the focus is on practical testing and the use of what has been learned. LSN makes use of the expertise of the cluster stakeholders, which can be supplemented by external knowledge if required. LSN acts rather as a broker, who knows the real needs through his close contacts to the cluster stakeholders and initiates training concepts and organises expertise.

The LSN ACADEMY will be further developed in the short term.

> Peer-to-peer exchange "personnel community" within the LSN e.V.

Future work in an increasingly digitalised world will significantly change the working environment and thus also personnel management and development. There are no standardised concepts for this yet. It is therefore planned that LSN will organise an exchange of information and experience between personnel managers and HR managers in suitable formats.

The measure has already been implemented and will be continued in the near future.

> Open Door/Experience Report/Get Smart

The strategy process has shown that practice-oriented mutual learning both within and outside the context of digitalisation is definitely desired among the cluster stakeholders. This includes both the demonstration of innovative digitalisation solutions by selected cluster stakeholders and the presentation of digital solutions by external parties that might be of interest to the cluster stakeholders.

The implementation will take place in the long term.

> Extension of the "LSN JOBS" job exchange to a career portal

The successful job exchange "LSN JOBS" is to be strengthened and further expanded in order to achieve professionalisation in its design as an online-based recruiting tool and to increase its overall reach. Possible measures are the implementation of an intelligent search function and the active application in the cluster as well as in selected positions.

An inventory will be taken in the short term. The creation of a concept for further development and the revision of the job portal are planned for the medium term. A concept to increase the reach is a long-term one.

> Expansion of LSN XCHANGE

LSN XCHANGE has been established as a digital platform for collaborative work and is used in particular by working groups, project groups and for passing on information about events. The functionalities are to be expanded in the future and, in particular, make it easy to find the competencies of companies, institutions and individuals.

Implementation will take place in the medium term.

> Competence development of international partnership

Even if the topic of internationalisation does not have its own goal or strategic field of action, as in the past due to its increasing cross-sectional character, it will nevertheless continue to play an important role. During the strategy process, it became clear that the various cluster stakeholders have detailed knowledge in the areas of international markets or admission requirements. Cluster Management will collect this knowledge in the sense of an intelligent partnership and make it available in a demand-oriented manner. The same also applies to the targeted establishment and expansion of international partnerships.

The measure will be implemented in the medium term.

FURTHER DEVELOPMENT OF A CULTURE OF INNOVATION AND ENTREPRENEURSHIP

LSN creates an optimal environment for innovators, founders and investors in the Life Science Sector. LSN works closely with the federal states of Hamburg and Schleswig-Holstein to coordinate the concepts and measures with the activities of the Ministry of Economic Affairs and the economic authority respectively.

It is not just a question of building up and offering financial support opportunities. The aim is to implement needs-based measures that provide the framework conditions for the sustainable and value-adding development of entrepreneurial ideas, but also lead to more inventions and innovations in established companies. This approach must also be marketed nationally.

The development of a pronounced innovation culture in existing companies and an improved start-up culture have a positive effect on the achievement of other operational goals.

OPERATIONAL GOAL 4

PLANNED MEASURES

> Expansion of activities around the topic "Regulatory Framework".

The strategy process has shown that the topic of Regulatory Affairs is currently one of the top topics in the cluster. At the same time, it is also regarded by many stakeholders as a major obstacle to innovation. The "Regulatory Affairs" working group is to be continued in its existing form. At the same time, however, the spectrum of activities is to be expanded so that Cluster Management can develop into a central point of contact (one-stop shop) that can refer questions relating to Regulatory Affairs to specialised partners (intelligent partnering). This also includes event formats on this topic.

> Establishment of a dialogue with hospitals/cost reimbursors

The aim here is to open access to the institutions responsible for reimbursement and medical needs for LSN members (stronger cooperation with the health industry, in particular the cluster organisation GWHH and equivalent in S-H). These dialogues could help to better understand the actual needs (medical needs), which then also serve as input for innovation ideas.

> Implementation takes place within the framework of ongoing projects.

> Measures to promote a culture of innovation in enterprises

This includes, among others, design thinking innovation dialogues in Life Science companies, motivation of employees to change their mindset with regard to innovation culture. These measures can also be integrated into the LSN ACADEMY program, while others are implemented by external expertise from selected partners.

Implementation takes place within the framework of ongoing projects.

> Establishment and operationalisation of strategic partnerships with relevant institutions

In order to make a contribution to improving the start-up culture, Cluster Management will initiate or expand active cooperation with key stakeholders in the start-up scene (e.g. support structures at universities and research institutions, incubators, accelerators). The cooperation is guided by the principle of not offering consulting services in duplicate structures, but bringing in Life Science-specific expertise. Possible measures could be: sensitisation/encouragement of potential founders or advice on the market environment and general conditions.

The implementation will take place in the short term or has already partially begun.

> Expansion and increased communication of support services for start-ups

LSN will continue to expand and communicate its own expertise in advising founders and start-up investors, particularly in the areas of market data, regulatory framework conditions and the mediation of cooperation partners. The concept, service and communication instrument development will take place in the medium term. The implementation of the communication concept and the resulting consulting projects is to be regarded as rather long-term.

> Expert pool for the evaluation of business plans

As a seal of quality for innovative start-up ideas from the region, evaluations of business plans are to be drawn up by a neutral pool of experts. This quality seal is intended to make it easier for founders, supported by LSN, to gain access to investors or financiers. The experts are to be recruited primarily from LSN entrepreneurs.

The development of a concept for implementation will begin in the short term.

> Facilitating access to finance

As access to funding is particularly critical for both innovation projects and Life Science start-ups, LSN will continue to seek to support innovators and founders in this context. This includes the examination of new sources of financing for the members and the establishment of an investor network.

The implementation will take place in the long term.

COOPERATION BETWEEN INDUSTRY AND NEEDS-ORIENTED SCIENCE

The future challenges of the industry require an intensive, result- and demand-oriented cooperation of the stakeholders from economy and science. The activation and promotion of cooperation between universities, university clinics and non-university research institutions (hereinafter collectively referred to as "public research") with (regional) commercial enterprises is a central building block for the work of LSN. Whereas in the past the primary goal was to bring business and science together at all, in the future this cooperation should be seen more as a means to an end to increase the output of innovations or to better solve technological challenges. The initiation of interdisciplinary cooperation, also with cross-sectoral character, will become more important.

The public research stakeholders have established their own structures for efficient technology transfer. LSN's Cluster Management will complement the activities with meaningful measures based on expertise and the Life Science Network and the pooling of interests and needs of individual technology transfer institutions.

OPERATIONAL GOAL 5

PLANNED MEASURES

Successful cooperation between science and industry plays an important role in various other operational objectives. The success of the test field approach depends crucially on the different stakeholders working together in a result-oriented way. Improved access to knowledge and expertise in the cluster also depends on the willingness of the stakeholders to cooperate (see also Operational Objective. 3). A successful further focus in the LSN Cluster depends on the intensive involvement of universities, university clinics and non-university research institutions. The relevant measures that the Cluster Management will develop and implement will not be repeated separately at this point.

> Intelligent Partnering

LSN Management will continue to bring together the right partners from business and academia through event-driven consulting. This also includes the conception of projects and the recommendation of funding opportunities.

The first steps towards implementation will begin shortly.

> Cross-Clustering

Within the framework of the strategy process it became clear that for many problems, especially at the beginning of the innovation pipeline, very different competences are necessary in order to record rather unusual solutions. Therefore, new event formats/"marketplaces" are to be developed in which the needs of companies are brought together with the competences of science.

The implementation will take place in the long term.

> BRIDGE Concept

The development of capital-intensive, high-risk and long-term products, such as new active substances, is particularly dependent on new forms and frameworks of cooperation. Here, innovative ideas from science are to be brought together with the industrial competence of the companies at a very early stage in the development process and, through targeted project funding, further developed into a decision point where further steps (e.g. foundation, licensing or abandonment) can be decided on the basis of valida-ted data. Here the bundling of several research and industry partners and their expertise is essential in an established framework.

The BRIDGE concept will be expanded in the short term as part of ongoing projects.

MAKING LSN MORE USEFUL AS A THINK TANK FOR REGIONAL DEVELOPMENT

LSN Management continues to support the stakeholders of regional development in shaping the future framework conditions for the Life Science Sector in Hamburg and Schleswig-Holstein. As a joint representative of business, science and politics, LSN will from now on be even more actively involved in strategic and content-related issues relating to regional development, with the aim of bringing current trend topics, needs, challenges and developments in the cluster to the attention of the responsible decision-makers. LSN is thus developing from a pure implementer and advisor to a thought leader who is actively involved in questions of regional development.

For example, cross-sectoral topics relevant to regional development, such as intelligent production technology, are to be promoted across departments and clusters. LSN should generate ideas and develop concepts for this.

OPERATIONAL GOAL 6

PLANNED MEASURES

> Active participation in the updating of regional innovation strategies from 2021 onwards Regional innovation strategies, so-called Smart Specialisation Strategies, continue to be a prerequisite for the next Structural Fund period of the EU. In this context, both federal states will update their current strategies. LSN will make an active contribution to ensuring that the challenges of the industry are adequately addressed and appropriate policy instruments developed.

The measure will be implemented after consultation with the political decision-makers.

> Cross-border representation of interests on selected topics

In the past, LSN Management has actively discussed and clarified the interests of the cluster stakeholders in selected topic areas with representatives of regional development. LSN will further develop this role and, in coordination with the relevant stakeholders integrated in the cluster, strengthen the interests of members. "Regulatory Affairs", for example, is a highly relevant topic from the point of view of the cluster stakeholders.

The measure is already being implemented and will be continued in the future in line with demand.

> Moderation master plan "Innovative Production Technology" for the federal states of Hamburg and Schleswig-Holstein

Innovative production technologies play a decisive role in various industries relevant to Hamburg and Schleswig-Holstein. The economic footprint has shown how high the added value is in the region. The LSN Cluster, in close coordination with other clusters in the region, will draw up a master plan on how production technology at the site can be sustainably strengthened.

Implementation is planned for the long term.

THE FUTURE GUIDING PHILOSOPHIES OF CLUSTER MANAGEMENT

LSN Management assumes the central controlling and executive role within the framework of the LSN Cluster Strategy 2024. Due to the ever more complex challenges in the Life Science Sector, the task portfolio of cluster stakeholders is also becoming more demanding and interdisciplinary. This requires a versatile understanding of the roles of the responsible stakeholders. In order to do justice to this, four essential guiding philosophies for Cluster Management will be implemented as part of the strategy, which will shape the future spectrum of actions and services (see Figure 7). They also represent the key to success for the successful implementation of the strategy together with the cluster stakeholders.

Figure 7: Philosophies of Cluster Management



SUSTAINABLE CLUSTER MANAGEMENT

The aim is to ensure the long-term success of the companies and research institutions of the LSN Cluster and thus of the entire site through sustainable Cluster Management. Sustainable management here means the efficient and targeted use of private and public funds to promote the competitiveness of the cluster stakeholders.

New instruments and services are to be used to ensure sustainable Cluster Management. Digital tools such as LSN XCHANGE will continue to be used and expanded for this purpose. Digitalisation should not only be used to improve the networking of members, but should also help to make the processes within LSN Management more effective. This also includes building up own competence in Cluster Management only where no suitable cooperation partners or cluster stakeholders exist. Thus, the aspect of sustainable Cluster Management is also closely related to the other guiding philosophies.

NEEDS-BASED RANGE OF SERVICES

LSN is committed to providing its members with a range of services that meet their needs. This includes not only classic services such as knowledge transfer, general networking measures, or marketing activities, but also opportunities for more in-depth cooperation and innovation measures in selected key areas.

In order to realise such a portfolio, the trust of the cluster stakeholders among each other must be further strengthened. At the same time, the needs of the members must be constantly recorded in order to make continuous adjustments to the measures and services of Cluster Management. In addition, complex cooperation projects require additional expertise from the Cluster Management, which is to be successively built up and expanded.

INTELLIGENT PARTNERING

Limited resources with a simultaneously higher demand on LSN Management, which results from the manifold and increasingly complex challenges, inevitably leads to the need to increasingly fall back on the external competencies of cluster stakeholders and other partners. An intelligent partnership should determine the entire action of the Cluster Management. This includes, above all, knowing the core competencies of the cluster stakeholders and establishing a relationship of trust so that the willingness to share this knowledge grows. It also means bringing together the cluster stakeholders who have a concrete problem or question quickly and specifically with those who have the appropriate problem-solving competence.

This will also change the role of Cluster Management in that it will play an even stronger coordinating role in the implementation of projects than before. Pure project management is increasingly becoming intelligent stakeholder management.

FOCUSED BRANDING

As a major challenge within the framework of the strategy process, a clearer visualisation and profiling of the core competencies of LSN was cited – both within the clusters and in the international context. Sustainable LSN Management, which develops and implements needs-based services in cooperation with various partners, creates the right conditions for this. The future measures will be characterised by the offensive communication of the underlying technological competencies in the selected thematic focal points. In addition, more expertise must be built up in the field of digitalisation and the existing expertise must be made more visible to the outside world in order to perceive LSN and the region more strongly from the outside as a "digital location in the Life Science sector". Public relations and marketing campaigns must be geared to this and also conceived with an international focus.

The strengths and successes of the LSN Cluster will have to be actively marketed nationally and internationally in the future, thus advancing the branding of both the cluster and the Life Science region. A coordinated portfolio of individual communication activities contributes significantly to the generation of a Unique Selling Point (USP), which makes LSN visible beyond national borders as a digital Life Science Cluster leading in specific technological topics and thus also increases the attractiveness for specialists, start-up candidates and companies.

IMPLEMENTATION PLAN

The successful achievement of the formulated strategic and operational goals requires an extensive service portfolio on the part of LSN Management, which is implemented jointly with the members. The measures formulated in Chapter 5 (Operational objectives) are a mixture of both existing and new measures. Within the framework of the implementation of the LSN Cluster Strategy 2024, it is therefore important to ensure that what has been tried and tested so far is continued and that the new measures are implemented appropriately.

Some of the new measures are already clearly delineated or represent a continuation of proven measures. Their implementation can take place at short notice. Others, however, require careful conception, sometimes with the active involvement of selected members, even in the development phase. This must be developed within the framework of day-to-day business and must not be at the expense of the quality of LSN Management's work.

Other measures, such as the construction and operation of test fields, require separate financing from third parties, as these involve considerable time and financial costs for Cluster Management and the members involved. Their launch and implementation therefore depend on the availability of the corresponding financing sources. The implementation plan thus has both a short-term and a medium-term component, as indicated in Chapter 5.

The internally developed implementation plan serves LSN Management as a central work and orientation basis at the operational level. It is actively supported by an internal monitoring and indicator system, which helps to ensure a goal-oriented and efficient implementation of the strategy. Due to the long-term orientation of the strategy until 2024 and the ever faster changing framework conditions, the monitoring of the implementation plan is of great importance.

REVIEW PROCESS

8.1 SUCCESS AND IMPACT MONITORING SYSTEM

The LSN Cluster Strategy 2024 is undoubtedly ambitious. Implementation requires an appropriate mix of the continuation of the tried and tested together with completely new elements, e.g. test fields or closer cooperation with stakeholders beyond the original boundaries of the core area of Life Science. In order to ensure a contribution to the successful and sustainable implementation of the strategy, LSN Management will introduce success and impact monitoring. This should also help to better document the success of the cluster work with the LSN Stakeholders than in the past.

The success and impact monitoring of LSN Management should therefore primarily pursue two goals:

- > It shall be a practical control instrument for the implementation of the LSN Cluster Strategy 2024.
- > It should identify effects and successes and make them visible for all those involved.

The monitoring system should not be understood as a control instrument that divides results into "good" and "bad". Rather, it should be understood as an active steering instrument for LSN Management and the corresponding committees in order to identify possible undesirable developments with regard to the planned operational achievement of objectives as well as to point out successes and effects achieved.



The monitoring system to be set up should be able to establish a causal relationship between input (e.g. resources made available or LSN Management's work performance), measures and output (activities, services produced) as well as outcome (the intended results among the target group of cluster stakeholders). The long-term results of Cluster Management activities can then be documented as impact. These can sometimes occur much later and cannot be directly influenced by an LSN Stakeholder or intervention.

In order to achieve the desired practical informative value, the monitoring system to be set up should meet the following requirements:

> Appropriate mix of methods

Both quantitative and qualitative indicators are used in different survey methods at the same time.

> Individual consideration of LSN

The concept must take into account the peculiarity and the specific challenges of the LSN Stakeholders and the industry as well as the strategic and operational goals of the LSN Cluster Strategy 2024.

> Accepted and transparent approach

The monitoring concept is developed in close coordination between the Cluster Management and the Supervisory Board, in which the funding bodies of both states are also represented.

At the same time, the result and impact monitoring system

- > should not cause an unnecessarily high additional effort in the indicator measurement on the part of LSN Management,
- > should only use those indicators which also have a relation to the operational objectives,
- > should understand the selected indicators as integrative components of the control of Cluster Management,
- > should use indicators which measure the performance (output), effectiveness (outcomes) and sustainability (impact) of the supported cluster initiative.

The review process of the implementation of the LSN Cluster Strategy 2024 will be conducted during the Supervisory Board meetings. Corrections, if any, can thus be agreed as a result of the strategic discussions in the context of the Supervisory Board meetings.

LIST OF LITERATURE AND REFERENCES

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APPENDICES GERMAN CLUSTER INITIATIVES IN THE FIELD OF LIFE SCIENCE

Course description of comparable cluster initiatives from Germany

BIOCON VALLEY

BioCon Valley®

BioCon Valley is a cluster initiative for Life Science and health economy in Mecklenburg-Western Pomerania founded in 2001 with headquarters of the Cluster Management organisation in Rostock. A total of 16 people are employed in the Cluster Management organisation. The cluster initiative focuses on health economics, Life Sciences, medicine and medical technology, molecular biology, plasma physics, neurosciences and oncology, animal health, plant breeding (and its use in the bioeconomy), eHealth, healthy nutrition and health tourism. The content of the cluster initiative is therefore very broad, but the focus is on the health care industry and the research focus is on "Marine Biotechnology", "Personalised Medicine" and "eHealth." The activities are based on the "Masterplan Gesundheitswirtschaft Mecklenburg-Vorpommern 2020"10. In the BioCon Valley e.V. a total of 124 cluster stakeholders are involved, including 49 small and medium-sized companies, one large company and ten university and non-university research institutions.

10) Cf. see: Ministry of Economics, Labour and Tourism Mecklenburg-Western Pomerania (2011):

Further Information: www.bioconvalley.org

BIOLAGO – THE HEALTH NETWORK

BioLAGO – the health

BioLAGO – the health network, founded in 2007, is a cross-border cluster initiative in the Lake Constance region and covers neighbouring areas in Germany, Switzerland, Austria and Liechtenstein. The Constance-based Cluster Management organisation employs a total of six people. BioLAGO e.V. brings together 114 cluster stakeholders from the pharmaceutical, medical technology, diagnostics and Life Sciences sectors, including 89 small and medium-sized companies, ten large companies and 14 university and non-university research institutions. The research fields are diagnostics and analytics as well as laboratory automation. Through the close cooperation with cyberLAGO, digital Life Science applications are jointly promoted by the cluster stakeholders of both cluster initiatives. BioLAGO has an orientation that is comparable to that of the LSN Cluster in terms of both thematic breadth and the industries involved.

Further Information: www.biolago.org



BIO^M - MUNICH BIOTECH CLUSTER

The greater Munich area is one of the leading national and international biopharmaceutical locations. The Cluster Initiative BioMm [-Munich BioTech Cluster, which was founded in 1997, comprises more than 250 cluster stakeholders, including more than 200 small and medium-sized enterprises, 20 large enterprises and 15 university and non-university research institutions and technology parks. The thematic focus of the cluster stakeholders and the cluster initiative is the development of innovative therapies, diagnostics, immunotherapy, digitalisation of medicine and personalised medicine, i.e. they are to be located in the fields of biotechnology and pharmaceuticals. A total of 16 people are employed in the Cluster Management organisation.

Further Information: www.bio-m.org

BIO.NRW CLUSTER BIOTECHNOLOGY NORTH RHINE-WESTPHALIA

On behalf of the state government of North Rhine-Westphalia, Forschungszentrum Jülich has been operating the BIO.NRW state cluster office since 2008. The Cluster Management develops the BIO.NRW Cluster together with and for biotechnology companies, research institutions and biotechnology networks in North Rhine-Westphalia. The aim is to catalyse the sustainable development of the strengths of North Rhine-Westphalian biotechnology by creating an effective network for companies and scientific institutions. BIO.NRW functions as an event platform for Life Science topics, supports start-ups and SMEs, promotes technology transfer and acts as a contact partner for young scientists. BIO.NRW is financed by the Ministry of Economics, Innovation, Digitalisation and Energy of North Rhine-Westphalia as part of the state's cluster policy.

Further Information: www.bio.nrw.de/

BIOPARK REGENSBURG

The cluster initiative BioRegio Regensburg in Eastern Bavaria is managed by the BioPark Regensburg, which was founded in 1999. 14 people are employed in the management organisation. The cluster initiative includes more than 80 cluster stakeholders, 55 of which are small and medium-sized enterprises, nine large enterprises and 12 research stakeholders. The thematic focus is on the health care industry and biotechnology, but also on medical technology and pharmaceuticals. The main areas of research are immunotherapy, tumour research, eHealth, cell therapy and oncology.

Further Information: www.biopark-regensburg.de







BIOREGIO STERN | BIOREGIO STAR MANAGEMENT GMBH



The BioRegio STERN cluster initiative was founded in 2001 and comprises the Stuttgart and Neckar-Alb Greater Region with the cities of Tübingen and Reutlingen within the federal state of Baden-Württemberg. The Cluster Management organisation, which employs 8 people, is based in Stuttgart. Over 360 cluster stakeholders are involved in BioRegio STERN. These include more than 250 small and medium-sized enterprises, 27 large enterprises and more than 55 university and non-university research institutions. The STERN BioRegion brings together the existing expertise in the two areas of medical technology and biotechnology in this region. The thematic focus is on diagnostics and automation in biotechnology and laboratory automation.

Further Information: www.bioregio-stern.de

BIO RN NETWORK E.V.

In the Bio RN Network e.V. more than 200 stakeholders from the red biotechnology are involved. The Cluster Region is located in the border triangle of Baden-Württemberg, Hessen and Rhineland-Palatinate and encompasses the cities of Heidelberg, Mannheim, Ludwigshafen, Darmstadt, Frankfurt/Main and Karlsruhe. Among the 200 cluster stakeholders are more than 120 small and medium-sized enterprises, seven large companies and 16 university and non-university research institutions, as well as technology parks. The Bio RN e.V. was founded in 2008, the Cluster Management organisation, which employs five people, is based in Heidelberg. The research fields of the cluster stakeholders involved include a wide variety of sub-themes in the fields of biotechnology, pharmaceuticals, cancer research and molecular biology and medicine.

Further Information: www.biorn.org

BIOSAXONY E.V.



The biosaxony eV. is the cluster initiative for the fields of biotechnology and medical technology in the Free State of Saxony, with regional focuses in Dresden and Leipzig. The association, which was founded in 2009, involves more than 124 cluster stakeholders, including more than 56 small and medium-sized enterprises, two large enterprises, two universities and 12 non-university research institutions. The Cluster Management organisation, which is based in Dresden, employs nine people. The main research areas are Smart Medical Devices, Personalised Medicine and Diagnostics.

Further Information: www.biosaxony.com

CLUSTER GESUNDHEITSWIRTSCHAFT BERLIN-BRANDENBURG – HEALTHCAPITAL



The capital region Berlin-Brandenburg is one of the leading international locations in the fields of Life Sciences, health economy and health care and is characterised by a high concentration and networking of science, industry and clinics. The location is also characterised by the fact that the Charité is the largest European university clinic in the capital, as are the two client groups Vivantes and Helios as well as renowned clinics in the state of Brandenburg (including the Ernst-von-Bergmann-Klinikum in Potsdam and the Carl-Thiem-Klinikum in Cottbus) and nine technology parks with thematic references (e.g. Technologiepark Adlershof).



The Cluster Gesundheitswirtschaft Berlin-Brandenburg was founded in 2007 and is managed by a transnational Cluster Management, which is carried out by Berlin Partner für Wirtschaft und Technologie GmbH and Wirtschaftsförderung Land Brandenburg GmbH (WFBB). The capital region is regarded as a pioneer in the establishment of integrated care models (including the use of telemedicine in the Brandenburg region). The main topics include drug development, diagnostics, regenerative medicine, imaging, cardiovascular medical technology, new forms of care and rehabilitation. In total, more than 280 cluster stakeholders, including more than 130 small and medium-sized enterprises, are involved in the cluster initiative.

Further Information: www.healthcapital.de/en

MEDICAL VALLEY FUROPEAN METROPOLITAN REGION NUREMBERG

The cluster initiative Medical Valley European metropolitan region Nuremberg was founded in 2007 and comprises almost 200 cluster stakeholders. These include approx. 150 small and medium-sized enterprises, ten large enterprises, as well as university and non-university MEDICAL VAL research institutions. Eleven people are employed in the Cluster Management organisation, which is based in Erlangen. The Medical Valley European Metropolitan Region Nuremberg is one of the world's leading medical technology product categories for imaging diagnostics (computer tomography, magnetic resonance imaging, interventional imaging), therapy systems (ophthalmology, lithotripsy, eye lasers), telemedicine (medical information systems, homecare, tele-rehab, monitoring) and high-tech implants (cardiac pacemakers, revision implants).

Further Information: www.medical-valley-emn.de

TECHNOLOGY MOUNTAINS E.V. | MEDICAL MOUNTAINS AG

The Technology Mountains e.V. is a cross-industry association in the Schwarzwald-Baar-Heuberg region of Baden-Württemberg and covers the districts of Rottweil, Schwarzwald-Baar-Kreis and Tuttlingen. The support offered by the association consists of the services of the three main stakeholders MedicalMountains AG, Hahn-Schickard-Gesellschaft für angewandte Forschung e.V. and Kunststoff-Institut Südwest GmbH & Co. KG. The association was founded in 2005. They own over 240 cluster stakeholders, including over 190 small and medium-sized enterprises, 38 large enterprises and 15 university and non-university research institutions and technology parks. The focus in medical technology is on "cleaning in medical technology" and "regenerative medicine and bipolarisation".

Further Information: www.technologymountains.de | www.medicalmountains.de





www.lifesciencenord.de