OP 3.4.1

Regional development plans

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Summary	To ensure sustainability of the project each partner will develop a Regional development plan in order to show how the project can get access to the target groups (see 2.1 Relevance) of the regions.

Starting situation: Upper Bavaria`s results of WP3

SWOT of clinics and R&D institutions in upper Bavaria

Strengths: - Very intense cooperation between university hospitals and other healthcare stakeholders (e.g. with "big" industry, r&d institutions, politics, healthcare organisations) - Many clinics are certified and have a quality management system - High degree of consolidation processes; e.g. fusion of the 5 Munich community hospitals led to Städtisches Klinikum München Ltd. - Specialist clinics are available in the big metropolitan areas - Private-public networks (ambulant pharmacists-hospital) and cooperation of hospitals in rural areas - Various approaches for innovation-/technology transfer - Part of a big healthcare market especially in the European Metropolitan Region Munich - Resources for application of new, innovative and expensive MedTech products - High degree of process optimisation within hospitals; strategic departments - Well educated employees - Very good healthcare services for the inhabitants of Upper Bavaria - Outsourcing of services which are not hospital core function - Highest rates of patent applications in Germany	**Weaknesses:** - Still too many municipal clinics in rural areas (in Bavaria more than in other federal states of Germany), period of hospitalisation too long, hospitals - especially in rural areas - aren`t filled to capacity - Municipal hospitals have to save a part of their income (4,2% of annual turnover) for the pension of their employees - Most employees for the hospitals are trained in municipal hospitals - German bed capacity is bigger than average compared to other European countries (60%); bed capacity in Bavaria is smaller than the German average - Innovation management system still not introduced regionwide, even within university hospitals; it is just applicable for the hospital itself - Innovation transfer to SMEs not happening due to missing trust in their abilities and capacities - Coordination of technology transfer is still not process optimized (e.g. bottleneck BayPat) - MedTech innovations need high skilled personnel and higher cost for maintenance
Opportunities: - Competition of hospitals leads to chain-building, growth of privately owned hospital chains and cooperation-networks in rural areas; this leads to a better organization of healthcare services and resources - Better organization of healthcare processes: shorter hospitalization, better pre- and post-hospitalization (ambulant services, rehabilitation) - Introduction of eHealth systems will save hospitals time and money for the benefit of the patients - During depression keeping to the high tech strategy of German Government - Upper Bavarian politics is aware of the healthcare situation and coordinates their support wisely - Easier funding of investment in 2011 (NUBs) - Introduction of the innovation transfer system of IntraMED-C2C could generate a fund for reinvestment in innovation - Municipal hospitals educate the hospital staff of the future: they can choose the best fitting ones for their clinics; if this staff decides to be ambulant MDs these can commit their patients to the hospital they were educated - Involvement in cooperation projects (e.g. eHealth region Upper Bavaria, excellence cluster M^4) will promote technology transfer	**Threats:** - Piling up of orders (= innovation orders piling up) due to healthcare-political reasons (actually 20-30 billion €) - High cost pressure in healthcare system (DRG) leads to distinction for the same treatment/services between public and private insured patients: private patients are over-, public patients are underexamined - Too many MDs in metropolitan regions, too little in rural areas - Demographic change will lead to a cost explosion in the hospitals due to the more intensive care necessary; staff has to be hired and trained - Decline of well educated employees - Unclear political and legal framework; no planning security for the hospital management - decrease of public funding - Bankruptcy of many small, public owned or rural hospitals

Source: own inquiries

Target groups "clinics" and "R&D institutions": in Upper Bavarian hospitals 3 ways of innovation transfer dominate

1. Via *university hospital* linked *Technology Transfer Centres (TTC;* e.g. KTI for Hospital of the LMU Munich, TUM ForTe for the hospital of the TUM rechts der Isar*)* or specialized institutes with a high degree of technology transfer rates (Contractual research, collaborative research, structured partnerships can be found at *MITI* or *MIMED* among others, both Transfer Institutes for the hospital of the TUM Klinikum rechts der Isar); innovation transfer resulting from *university hospital`s patient care* still is rudimentary
2. *Non university hospitals*: via Quality Management System based KVP processes (continuous improvement process)
3. Via *R&D institutions* (e.g. *Helmholtz-, Max-Planck- and Fraunhofer-Institutes*)

Ad 1. In *university hospitals* there are two ways of handling innovations:

A. Innovations in *university hospitals* resulting from the R&D departments of the medical faculty. These innovations are further supervised by the university-attached *Technology Transfer Centres* like KTI (Ludwig-Maximilians-Universität München) and TUM ForTe (Technische Universität München). The Technology Transfer Centres advise their researchers and their research facilities on all issues from invention development to patenting to marketing the research findings. In spite of their efforts the output of the clinical inventions still is too little. The innovations are then furthered to the *BayPat*. The *Bayerische Patentallianz GmbH* is the central patent and

marketing agency of 28 Bavarian universities and universities of applied sciences and, as such, the link between science and industry. They evaluate and market the inventions of more than 17,000 scientists in Bavaria. They thus support the inventors in protecting their inventions and then using them commercially. They provide industry with unique access to the largest technology pool in Bavaria. Due to their broad field of duties they act as a bottleneck for innovation transfer.

Contractual research, collaborative research, structured partnerships:
The *MITI* is an interdisciplinary research group. It deals with the development of innovative diagnostic procedures and therapeutic solution concepts for minimally invasive surgery. The research group was founded in 1999 at the Klinikum rechts der Isar of the Technical University of Munich. The motivation is to develop patient friendly methods for diagnostic and therapeutic interventions, which are mainly applied in surgery and gastroenterology. Since its inception MITI sets value on interdisciplinary work. Competences from engineering, industry and the medical field meet and a know-how centre for medical technology emerges. Therefore, MITI is a reliable meeting point for everyone, who is looking for innovative solutions in the medical technology field. The range of products is focused on a narrow field only.

The Institute of Micro Technology and Medical Device Technology (*MIMED*) at the Technische Universität München is specialized in Precision Engineering, Micro Technology and Mechatronics Systems/Robotics. MIMED has a strong focus on applications in clinical engineering, rapid manufacturing, and assistance systems for an aging society. The institute takes part in many national and international research programs and is a strong partner in contract research for the industry. The range of products is almost ideal.

B. *University hospitals*` ideas and innovations resulting from *patient care*: identical with next item

Ad 2.
A quality system is generally stipulated in German hospitals to get the operation allowance. An integral part of it is the employee suggestion scheme. Certified clinics have to further develop the continuous improvement process as the key element of their quality management system. Ideas and innovations stemming from *university- and non-university hospitals* are mainly collected by the hospitals` quality management or IT department. Due to the commission to continually improve the hospitals` quality processes there are postboxes on every ward where patients and staff can contribute to the development of clinical quality. Only two of the evaluated clinics had a full time idea / innovation manager. A special innovation management software is implemented in one clinic only; usually paperborne systems are used. This system has to be further developed if ideas for products, processes and services shall be manifold.

Ad 3.
Contractual research, collaborative research, structured partnerships: Sometimes medical professors have a position both in universities and in R&D-Institutes like *Helmholtz-, Max-Planck- and Fraunhofer-Institutes*. The innovations or the patents are then promoted by an associated private company (e.g. exclusive partnership of Ascenion with Helmholtz foundation). The *Helmholtz Institutes* are structured as follows:

The Helmholtz Association is a community of 17 scientific-technical and biological-medical research centres. These centres have been commissioned with pursuing long-term research goals on behalf of the state and society. The Association strives to gain insights and knowledge so that it can help to preserve and improve the foundations of human life. It does this by identifying and working on the grand challenges faced by society, science and industry. In their longer-term research programmes, Helmholtz scientists seek to combine

theoretical basic research with perspectives for innovative applications and provisions for tomorrow's world. Numerous examples, such as the following, illustrate this: in the field of medical engineering and technology, Helmholtz scientists are developing systems and procedures to re-establish body functions impaired or lost as a result of organ failure, organ damage, trauma or age-related ailments.

Max Planck Institutes are built up solely around the world's leading researchers. They themselves define their research subjects and are given the best working conditions, as well as free reign in selecting their staff. This is the core of the Harnack principle, which dates back to Adolph von Harnack, the first president of the Kaiser Wilhelm Society, which was established in 1911. This principle has been successfully applied for nearly one hundred years. The Max Planck Society continues the tradition of its predecessor institution with this structural principle of the person-centered research organization. The currently 80 Max Planck Institutes conduct basic research in the service of the general public in the natural sciences, life sciences, social sciences, and the humanities. Max Planck Institutes focus on research fields that are particularly innovative, or that are especially demanding in terms of funding or time requirements. And their research spectrum is continually evolving: new institutes are established to find answers to seminal, forward-looking scientific questions, while others are closed when, for example, their research field has been widely established at universities. This continuous renewal preserves the scope the Max Planck Society needs to react quickly to pioneering scientific developments.

The *Fraunhofer Society* develops, implements and optimizes processes, products and equipment until they are ready for use and for the market. They work in all the application-relevant fields of expertise for contractual partners from industry and the public sector. The Fraunhofer-Gesellschaft has consistently built up its structure on research groups. Flexible interlinking of expertise and capacities enables the institutes to meet extremely broad project requirements and complex system solutions.

Core outputs and regional development plan for target groups “Clinics” and “R&D institutions”:

- A dedicated innovation manager should be responsible for a centralized and softwareborne innovation management system within clinics; contacting the relevant staff is up and running = enhancement of internal pool for ideas for the transfer to companies
- IP management processes within university hospitals should be accelerated and facilitated; contacting the relevant staff is up and running; non-university clinics should be educated in IP and patent right; contacting the relevant staff is up and running
- Contractual research, collaborative research, structured partnerships: encouraging SME`s to cooperate with R&D companies/university hospitals promoted by special regional/national/european subsidy programmes (e.g. go Inno = national innovation vouchers; transnational = State aid for R&D & Innovation RDI, Framework programme FP7, Competitiveness and Innovation Programme CIP); contacting the relevant staff is up and running
- German healthcare system: NUB`s facilitate the remuneration of innovations

Due to the broad network of the Forum MedTech Pharma depicted on page 6 it has been possible to contact the relevant target groups on different levels and to promote the project in clinics and R&D institutions.

At the initial workshop at the Helmholtz centre Munich it was shown that the bottleneck BayPat has to enhance its output. As BayPat is a non-exclusive option for universities regarding patent issues the universities should get in contact with other patent offices in

order to patent their ideas. Furthermore the organization of the innovation management at university hospitals has to be rearranged. There should be more education in patenting and IP-management.

This already started approach will be followed by inviting the target groups of the TTCs of the university clinics Munich Rechts der Isar, university clinic Großhadern and of university clinic Regensburg and the SMEs to the pilot innovation workshops, or by organizing a pilot innovation workshop in collaboration with the TTCs. The matchmaking with the SMEs will be organized by the Forum MedTech Pharma. By contacting and meeting the in reporting period 1 already contacted persons from the TTC and university hospitals, inviting them to become a member of the local steering group and organizing pilot innovation workshops the project will become a vital approach to innovation transfer in Upper Bavaria.

At meetings with key players of non university hospitals it was shown that the QM system in clinics is focussed on standardization and process optimization. Certified clinics have to further develop their QM system into an idea and innovation management system. But this is happening not too often (2 out of 45 innovative Upper-Bavarian clinics). This KVP approach will be followed by supporting the further development of their idea and innovation management system and by organizing pilot innovation workshops with the responsible QM managers and SMEs. Contacting and meeting the in reporting period 1 already contacted persons from the QM – KVP department, inviting them to become member of the local steering group and organizing pilot innovation workshops will again lead to a vital approach to innovation transfer in Upper Bavaria.

Due to the cooperation of InTraMed with Alps Bio Cluster there are good contacts to the target group of the Helmholtz centre in Munich. Therefore a pilot innovation workshop with stakeholders of the Helmholtz Centre Munich and of Ascenion, and of SMEs will be planned at first, later on with the Fraunhofer Society or the Max-Planck Institution. Organizing pilot innovation workshops with the target group in R&D institutions and SMEs will enhance their portfolio of SMEs and raise interest of cooperation projects between the SMEs and R&D companies.

Additionally the actual status of a possible (pilot-) innovation workshop will be constantly checked: are there enough ideas of a clinical thematic field, are there enough SMEs in this field, are there realizable dates et cetera.

Target groups “SMEs” and “other relevant groups”

Core outputs and regional development plan for SMEs and other relevant groups:

- Innovation management systems established in companies, rare in clinics
- In general: invention and patenting processes have to be communicated in detail with the inventors in clinics = motivation; contacting the relevant staff is up and running
- Patents: German employee invention act valid for companies, for clinics it depends on the legal form respectively whether it is a university hospital
- Inventions not applicable for patents: know-how as IP (smaller process or product improvements, the latter in cooperation with companies)
- Time-to-market from idea to finished product is far too long (7-9 years) and the costs are high (due to regulations, esp. Medical Device Directive)
- A better system of R&D funding & unbureaucratic remuneration has to be implemented (EC/national funding, facilitated NUBs); contacting the relevant staff is up and running

Due to the broad network of the Forum MedTech Pharma depicted on the next page it has been possible to contact the relevant target groups on different levels and to promote the project in SMEs and other relevant groups.

At the pilot innovation workshop the target group of SMEs (among others: in reporting period 1 already contacted persons) will be invited according to the competencies needed for the further development of the clinic`s ideas. It is to be discussed whether other relevant groups should attend the pilot innovation workshops.

The lead partner Forum MedTech Pharma was founded 1998 as an initiative of the Bavarian Ministry for Economic Affairs. As an interdisciplinary platform for all involved in medicine and in the health care system it has since then built up an independent network for information, communication & cooperation. Different co-operative projects of translating ideas and innovations into production prove the success of Forum MedTech Pharma in this field.

Via the regular Forum MedTech Pharma activities One-on-One Partnering Event MedTech & Pharma (2y), Conferences (altern. 2y), symposia, meetings with concomitant exhibition, joint boothes at international fairs, courses and seminars, workshops and general assembly it is possible to meet the decision makers and key players of the SMEs, health care insurance companies, health care decision maker groups and relevant political groups personally. About 500 contact persons of companies and other relevant groups and about 130 contact persons of clinics and R&D institutes are members of Forum MedTech Pharma.

Members: companies, clinics/MD, R&D institutes, associations, private, (patent-) lawyers