Kappa Health

THE VOICE OF BIOMEDICAL SMEs

PERFORMANCE FACTORS IN MOVING FROM RESEARCH TO MARKET

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PERFORMANCE FACTORS IN MOVING FROM RESEARCH TO MARKET

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A publication supported by the European Commission

KAPPA-Health

The KAPPA-Health project endeavours to assess and showcase the success of biomedical SMEs, which have received funding from the European Union Framework Programmes (FPs) for research and technological development sixth and seventh. The KAPPA-Health project includes seven project partners of which five are also SMEs. All partners offer complementary knowledge and experience of EU Framework Programmes, managerial issues, financial markets and an awareness of the challenges that SMEs are facing in achieving commercial success through their research results.

Legal notice

FOREWORD

Dr Ines Haberl, Coordinator of the Fit for Health project

FFG, Austrian Research Promotion Agency
European and International Programmes

Small and medium-sized enterprises[1] (SMEs) are widely recognized as the "backbone" of the European economy: They represent more than 99% of all European businesses and approximately two thirds of all European jobs. And although SMEs active in life sciences and biotechnology represent only a small fraction of the European SME landscape, they increasingly play a central role in important economic sectors such as healthcare and pharmaceuticals, or industrial processing. In particular in the fields of healthcare and biotechnology a rather large proportion of research-intensive SMEs can be identified. In response to challenges like insufficient supply of risk capital and shortcomings in the cooperation between science and business, one of the main objectives of the 7th Framework Programme (FP7) is to provide European SMEs with a competitive advantage in the global market by improving their access to scientific knowledge gained by universities and research organisations.

SMEs are encouraged to participate in FP7, aiming at an SME participation rate of 15% (both in terms of number of participants and the share of FP7 funding), with a focus on research-intensive SMEs. A stronger participation of SMEs in European research and development (R&D) should also increase the overall research spending in Europe to 3% of GDP ("Barcelona target").

The main objective of the KAPPA-Health project was the identification of tangible ingredients of success and their consequences in terms of strengthening the capacity of SMEs to better exploit the results of the research conducted by FP6 and FP7 projects. This book shortly describes and analyses the 3-year investigation conducted among research-intensive SMEs that participated and terminated FP6-FP7 Health research projects.

Importantly this booklet gives a voice to SMEs, thus putting them on stage and increasing their visibility and recognition to the scientific community.

The necessity to provide a platform for SMEs, presenting their expertise to the research community is of outstanding importance and has been successfully demonstrated by related initiatives like the support actions "SMEs go Life Sciences" and "SMEs go Health" (conducted under FP6) or the currently running support initiative "Fit for Health". In contrast to researchers from universities or research centres, SMEs have additional needs in establishing networks and being identified for potential collaborations in FP projects.

Based on interviews with 83 SMEs, the booklet shows different success factors out of the SME participation in FP6 or FP7 projects. 92% of these SMEs are stating their participation in a FP-project as success or partial success and EU funding was crucial requirement for conducting research. Success factors can therefore clearly serve as recommendations for less experienced SMEs, like newcomers to the FP. Out of the most important success factors SMEs confirmed that the projects should be aligned with the core activities in their companies. The collaboration with important networks as a result of participation has been stated as well as the commercialisation of new products or services, allowing the access to new customers and markets. The generation of interests from investors and the increasing skills of employees have been mentioned.

SMEs prefer to participate in small projects, enabling close communication between project partners. The role of SMEs in projects should be in accordance with their skills and experience, taking an active role in the consortium. Especially for SMEs as coordinators, special training sessions would be appreciated.

However, the analysis also allowed the identification of still remaining obstacles SMEs are faced with when participating in such collaboration projects and the results out of this analysis could perfectly serve as a basis for further developments. In particular, bridging the financial gap between new scientific knowledge and technology which is generated within EU projects and their conversion into new products and services ready for the market still remains a barrier for many

[1] Enterprises qualify as micro, small and medium-sized enterprises (SMEs) if they fulfil the following criteria: < 250 employees, turnover ≤ €50 million turnover, balance sheet ≤ €43 million

SMEs. A proper dissemination plan and distinct regulation of intellectual property rights (IPR) and exploitation is of outstanding importance for SMEs and needs to be defined in detail already before a project is initiated. This will allow SMEs to protect their rights and be considered as equal partner in the consortium. The amount of administration within the projects should be diminished and main focus should be put on research and exploitation.

SME participation in the FP is still a challenge and will require measures of high leverage.

Some of the FP7 programmes started the implementation of additional needs for SMEs in their work programmes: in the programme "Research for the benefit of SMEs" under the Capacities programme, a "Demonstration Action" has been launched already in the 2011 Work Programme. It allows proving the viability of new products or services developed in a preceding "Research for SMEs"-project, offering a potential economic advantage but without direct commercialisation as further technological or other developments are required.

An analysis like the one presented by KAPPA-Health might help to facilitate and accelerate the already initiated process of simplification. Experiences from SMEs showed that the consideration of all phases of the innovation process should be taken into consideration when designing the next Framework Programme.

Dr Ines Haberl,
Coordinator of the Fit for Health project
FFG, Austrian Research Promotion Agency
European and International Programmes

SUMMARY

Why measure the success of Biomedical and Med-tech SMEs participating in EU Framework Programmes research projects and assess key performance factors for moving from research to market?

Over the last several decades, technological advances have enabled the development of new products and services to prevent, diagnose and treat a multitude of diseases.

SMEs are the main drivers of innovation and new biomedical applications in the Healthcare sector. However, despite substantial progress in biomedical research, commercialisation of new biomedical products and services remains a difficult task.

Entrepreneurs may be eager to commercialise their inventions but, while there are a number of obstacles to brining medical products and services to the market, one crucial factor often either makes or breaks commercial success: financing.

Healthcare biotechnology is, more often than not, a casualty of lacking financing since it can take over a decade of product development before a product hits the shelves. Businesses in this area need external funding for extensive periods of time to sustain high-quality research and development activities.

Obtaining public funding is one way of bridging the financing gap and increasing the chances of survival for high-tech SMEs. The European Union Framework Programmes for Research and Technological Development are one source of these funds.

The European Commission funded KAPPA-Health project focused on assessing research-intensive SMEs that have participated in 6th and 7th EU Framework Programme (FP) projects in the Health Theme. The objective of the research was to measure how successful SMEs were in their project participation and to analyse how SMEs exploited the results generated through their participation in a research project funded by Framework Programmes.

During the project, key success factors for participating in EU research projects were identified. These factors were deemed to be crucial to an SME's ability to exploit project results and to prove the viability of new technologies for commercialisation. These factors will be used to help candidate SMEs improve their chances of success when they enter into a FP project.

This report describes the findings of the investigation carried out in the framework of the KAPPA-Health project. The findings are then used to establish guidelines for new EU FP participants to help them build a successful EU project and derive the maximum benefit from the results.

INTRODUCTION

INTRODUCTION

Healthcare biotechnology and medical technologies in Europe

Over the last decades advances in healthcare biotechnology and bioengineering have provided a multitude of possibilities for new markers, drugs, vaccines and therapeutic applications to prevent diseases, make diagnosis and provide new therapeutics. The knowledge progress in healthcare biotechnology served the progress in medical technology which is responsible for increasing life expectancy in many disease areas, improving the quality of life of individuals with chronic medical conditions and allowing them to remain integrated, valued and productive. It also provided dramatic advances in how acute or chronic conditions such as cardiovascular disease, cancer or auto-immune diseases are managed.

The advances provided by medical technology are also helping to increase the efficiency of healthcare systems. The industry's continuous cycle of innovation and improvement is bringing new solutions to existing challenges as well as addressing unmet medical needs.

In relation to human health, these new (bio)medical technologies could potentially prevent, treat and cure a wide range of diseases – some of which today are considered to be 'incurable'. Among these are heart conditions, multiple sclerosis, various cancers, cystic fibrosis and leukaemia[2]. The potential of healthcare biotechnology for the development of better and more accurate diagnostics, and for designing improved therapies and vaccines is well recognised by the pharmaceutical industry.

Based on figures from a Commission survey, 51% of European biotechnology companies are involved in health-related activities, while other sources estimate that over 80% of biotechnology activity in Europe is healthcare-related[3]. The importance of the biomedical healthcare sector in relation to the pharmaceutical industry is also growing: medicines deriving from biotech innovations (biopharmaceuticals) are estimated to account for approximately 20% of all marketed medicines, and represent around 50% of all new medicines in the pipeline[4].

Healthcare biotechnology and medical technology innovation involves high-cost and high-risk long-term investment. As a result, around 87% of biotech SMEs worldwide are in the pre-profit phase as a natural consequence of their business model. Many of these organisations are micro-enterprises consisting of 10 or fewer employees and the administrative burden of participating in R&D programmes is often beyond their capacity[5].

Although the European and US biotechnology industries have approximately the same amount of companies, the US sector employs twice as many people, spends around three times as much on Research and Development (R&D), boasts of twice as many employees involved in R&D and raises twice as much venture capital[6].

For the med-tech sector, according to EUCOMED[7], there are around 22,500 medical technology companies in Europe; of these some 80% are SMEs employing less than 250 people; the total number of people employed approaches 500,000. These technologies go beyond the biomedical sector and include around 500,000 medical technologies currently available to healthcare professionals, ranging from syringes and bandages to orthopaedic implants and pacemakers.

Research funding in Europe

R&D is a key factor for long-term sustainable growth both economically and as related to quality of life. Faced with an aging population and strong competitive pressures from globalisation, Europe's future economic growth and jobs will have to come from innovations in products, services and business models. This is why innovation and R&D have been placed at the heart of the Europe 2020 strategy[8], the growth strategy of the European Union (EU) for the next decade. Key goals have been identified to advance Europe as a competitive economical power, create more and better workplaces, and enhance social cohesion.

[2] EuropaBio, Healthcare Manifesto, http://www.healthcare-manifesto.org
[3] European Commission, MEMO/05/389, 21 October 2005, http://europa.eu/press_room > Press release archive – Rapid
[4] European Commission, http://ec.europa.eu/enterprise > Industry sectors > Biotechnology
[5] EuropaBio, "Red biotech innovation in Europe", Ludovic Lacaine, Director of Healthcare Biotechnology http://www.innovationeu.org > Archive > Innovation EU Vol2-1 > BIO INNOVATION 2010 SUPPLEMENT > Red biotech innovation in Europe
[6] The European Association for Bioindustries, Biotechnology in Europe, 2006 Comparative Study http://www.europabio.be > About Biotech > Facts and Figures > Critical I 2006 study
[7] Eucomed represents the medical technology industry in Europe. Eucomed members include both national and pan-European trade and product associations as well as medical technology manufacturers. (www.eucomed.org)
[8] European Commission, Innovation Union, http://ec.europa.eu/research >Research Policy > Innovation Union

With this in mind, Europe needs to generate more impact from research and innovation funding. Obstacles remain in transferring research from the laboratory through to the development, commercialisation and application phases. One of the major instruments for overcoming these obstacles and reaching these goals is the European Union Framework Programme for Research and Technological Development (EU FP).

EU FP, by far, is the most important European instrument for funding research in academia, industry and small and medium enterprises. Framework Programme 1 (FP1) started in 1984 with a budget of €3.3 billion. In comparison, the budget of the current FP7 (2007-2013) is estimated to be around €53.5 billion and supports research, technological development and demonstration activities across the European Union.

One of the research priorities of FP7 is the Health Theme aimed at improving the health of European citizens, increasing the competitiveness and boosting the innovative capacity of European health-related industries and businesses while addressing global health issues including emerging epidemics. The emphasis of the Health Theme is on translational research i.e. clinical applications including scientific validation of experimental results, development and validation of new therapies, methods for health promotion and prevention (promotion of child health, healthy ageing, diagnostic tools and medical technologies), as well as sustainable and efficient healthcare systems. The Health Theme is most relevant for the biomedical sector and has the second highest funding budget after the thematic priority Information and Communication Technologies (ICT).

Annual Work Programmes for each priority are the basis for the execution of the overall Framework Programme. Research objectives are provided top-down by High Level and Advisory Groups composed of representatives of academia and industry. Their recommendations to the European Commission flow into the planning of the Work Programmes. In addition, there are also specific instruments for SMEs which are planned bottom-up with open research topics.

According to the sixth progress report on SMEs participation dated autumn 2010, around 11'000 organisations have so far taken part in FP7. Several organisations are engaged in more than one FP7 Grant Agreement (= project). Surprisingly, SMEs are the "highest single group participating in FP7" and account for 35.4% of the participating entities. However, in the Health Theme, only 10.8% of the EU Contribution is actually going to SMEs[9].

SMEs and their participation in European research

SMEs, including high-growth SMEs, make important contributions to job creation and productivity growth in the OECD area[10]. Research-based SMEs play a key role in pioneering and developing new technologies and markets. Many SMEs in healthcare biotechnology have become success stories that were often acquired by large pharmaceutical industries and are very important contributors to the European economy.

Investment in biotechnology and biomedical sectors is time and capital intensive and the sectors are subject to substantial risk and uncertainty. Consequently, early-stage companies face difficulties accessing sources of capital during the innovation phase, before product development is very advanced and some risk is mitigated.

As healthcare biotechnology became an area of strategic importance, access to financing has improved for healthcare research-intensive SMEs through the Sixth and Seventh Framework Programmes (FP6 and FP7). Originally developed to support academic pre-competitive research, the Framework programmes gradually opened to SMEs participation. In FP6 and FP7, SMEs are involved in many mainstream research projects.

Research budgets for biotechnology were emphasised in FP6 (2002-2006) and FP7 (2007-2013). Under FP7, approximately 15% of the funds were intended for SMEs, who also benefited from higher funding per project. Assistance to SMEs was also introduced throughout the proposal process in the form of, for example, help finding partners and advice on legal and financial issues by EC funded support services and dedicated expert networks[11].

[9] European Commission, "SME Participation in FP7 Report, Autumn 2010", Executive summary, http://www.eurosfaire.prd.fr/7pc/doc/1291041216_smes_in_fp7_autumn_2010_exec_summ_en.pdf
[10] OECD, "Small businesses, job creation and growth: Facts, Obstacles and Best Practices", 2010. - http://www.oecd.org/dataoecd/10/59/2090740.pdf
[11] Health-NCP net, Fit for Health, IPR Help desk

Public funding by the EU FP now accounts for 4-5% of the total investment in R&D in Europe. Projects funded under the FP bring together a critical mass of stakeholders with the aim to improve the health of European citizens and to boost the European economy.

Nevertheless, research-intensive SMEs that participate in Framework programmes continue to face challenges in exploiting project results. Despite the funding support of the EU, in almost all cases, additional capital or funding from other public sources, private investors or public-private partnerships are needed to bring biomedical discoveries to the market. Most biomedical SMEs have indeed a constant need for development capital to bridge the early stage funding gap and bring their product to a point where it can be marketed or out-licensed to a larger player.

SMEs, unlike academic or larger industry partners, are generally more focused on short-term results. Their work cycles are shorter, they are flexible by nature and many of them are constantly in 'survival-mode', looking for the next opportunity to inject more resources into the company. As a result, their R&D efforts are often more focused and business-driven and they measure success in terms of business results.

However, when it comes to public funding of innovative, high-risk R&D the measurement of success should be adjusted, especially in the healthcare biotechnology sector, to take into account that economic milestones can rarely be reached within the timeframe of a Framework project. Business success is clearly an excellent measurement of overall success but, in the context of public funding, this measurement should be expanded to take into account other factors such as improvement in the research management structure, expansion of human resources, generation of entrepreneurial skills and leadership, establishment of strategic alliances, adoption of translational research[12] and other improvements to the innovation process.

EU FP, being the most attractive public funding instrument for research-intensive SMEs today, is an excellent platform to explore these success factors and measure their impact on the innovative process.

The KAPPA-Health Project

The quantitative and qualitative success indicators for SMEs participating in R&D Health projects, and the contribution of these indicators to the evolution of a biomedical SME, have not been previously, thoroughly explored. The main objective of the KAPPA-Health project was to identify these tangible aspects of success and determine how they influence an SME's ability to exploit the results of research conducted within FP6 and FP7 projects[13]. A better understanding of success criteria can also aid negotiations with fund providers and contribute to narrowing the funding gap.

This report describes the findings of the investigation carried out in the framework of the KAPPA-Health project. The results presented in this report are based on answers collected via questionnaires and interviews from a sample of healthcare research-intensive SMEs involved in FP6 and FP7 projects funded under the Health programme. The analysis is based on responses from 83 SMEs, covering 120 FP6 and FP7 projects, whose projects were either completed or nearly completed at the time of data collection. The study presents their experiences in collaborating with other groups from all over Europe and provides guidelines for inexperienced and new EU FP participants for building a successful EU project and obtaining the most from the results.

[12] With its focus on removing barriers to multi-disciplinary collaboration, translational research is a paradigm for research alternative to the dichotomy of basic research and applied research. It is often applied in the domain of medicine but has more general applicability as a distinct research approach. See http://en.wikipedia.org/wiki/Translational_research

[13] KAPPA-Health itself has been a coordination and support action financed by the European Commission to carry out surveys and in-depth interviews with SMEs resulting in this booklet.

THE KAPPA-HEALTH STUDY

THE KAPPA-HEALTH STUDY

Approach

The basis of the KAPPA-Health project was the theoretical assumption that all SMEs that successfully participated in an EU-funded research project should share common qualitative and quantitative performance factors that contributed to that success. The main goal of the project was to identify the ten[14] most important success factors.

To this end, the KAPPA-Health consortium conducted a survey among research-intensive SMEs that recently finished a research project funded under the Life Science and Health (LSH) priority of FP6.

The survey was carried out in the following steps:

Step 1 *– Initial collection of potential factors contributing to successful participation*

Literature research and brain-storming sessions with stakeholders were used to compile an initial list of potential success factors and a questionnaire was designed for distribution to SMEs.

Step 2 *– Selection of SMEs for online survey*

The main target group for the survey was research-intensive high-tech SMEs in the biomedical sector that had recently completed an FP6 project. The European Commission provided a list, from their internal database, of all SME participants in FP6 and FP7 projects and their contact details. After a data integrity check and exclusion of SMEs not belonging to the main target group, a total of 343 SMEs were selected to participate in the survey. In addition, to collect general feedback from a wider group, SMEs in currently ongoing FP7 projects were also invited to fill in the questionnaire; however, this feedback was not used for the statistical analysis.

Step 3 *– Online survey with questionnaire*

As some of the selected SMEs had participated in multiple research projects, and there were multiple contact persons within the company, the e-mail request to participate in the online survey was sent to a total of 374 addresses within the selected 343 companies. The survey was sent in several batches, corresponding to the finish dates of the projects, between February 2009 and June 2010. The response rate of approximately 25% exceeded expectations and, after quality checks, a total of 83 questionnaires could be used for the analysis. These 83 SMEs had participated in 120 research projects.

Step 4 *– Selection of successful SMEs for in-depth interviews*

A subset of the 83 SMEs was selected for in-depth interviews designed to gather more insight in to the criteria for success. The selection was largely based on the companies' self assessment of their success within the research project and a review of the project outcomes.

Step 5 *– In-depth interviews with successful SMEs*

From January 2010 to January 2011, a total of 43 in-depth interviews were performed by the KAPPA-Health partners.

Step 6 *– Analysis and Interpretation*

The data collected during the online survey and in-depth interviews was processed and analyzed in order to elucidate common patterns, similarities and differences among the surveyed SMEs.

The findings are presented in the following pages. The key findings have been cross-checked and verified through consultation with stakeholders such as investors, SME support organizations and consultants. The views expressed during these consultations are presented in the discussion section towards the end of this report.

[14] Kappa = 10th letter in Greek alphabet

Complementary activities of the KAPPA-Health project

To encourage SMEs participation in the survey and interviews and to provide support to SMEs seeking financing, additional information about public research funds and/or Venture Capital was offered. Optional coaching sessions were also provided during interview visits. The first International Funding Forum (www.fundingforum.eu) was organised within the KAPPA-Health project. This was a major event where participants could get an overview of available public and private funding. Participants were also encouraged to participate in the KAPPA-Health survey.

Complementary to the survey and interviews, KAPPA-Health also organized multiple workshops at/or around international conferences. These workshops were used to present and evaluate preliminary results, discuss relevant key success factors for SMEs and to exchange best practices in terms of exploitation of project results.

The first International Funding Forum
12-13 June 2009, Zürich - Switzerland

Sample Selection

The results presented in this report are based on statements from 83 SMEs that participated in the survey and/or interviews.

Some key characteristics of this SME sample are as follows:

- They are research-intensive (48% are spending more than 50% of their budget on R&D)
- The majority are young enterprises (89% are less than 15 years old and 45% are less than 10 years old)
- They are rather small (77% have less than 50 employees and 35% have less than 10 employees)
- They are based in 18 different countries (15 EU member states and 3 associated countries)
- 50% of the SMEs in our sample are located in techno parks or university clusters
- 39% are spin-offs from universities and 8% are spin-offs from industry

The 43 SMEs that were considered the most successful and were selected for interviews have slightly different characteristics than the total sample:

- The successful SMEs spend a higher percentage of their budget on R&D (58% spend more than 50% of their budget on R&D)
- On average, the successful SMEs tend to be slightly older (77% less than 15 years old and 39% less than 5 years old)
- In line with their higher age, the successful SMEs tend to be slightly larger (68% less than 50 employees and 26% less than 10 employees)
- Coordinators are not located in a techno park or a business incubators
- University spin-offs appeared more often among successful project participants than Industry spin-offs; however, the sample size for this subgroup is too small to verify this statistically
- 70% of successful SMEs have participated to several FP projects
- 65% have regular revenues

We have identified two clusters of successful SMEs:

- SMEs from biotech services and non therapeutic sectors are coordinators or part of project initiators of STREP[15] projects
- SMEs from biotech therapeutics and pharmaceutical sectors that are invited to reach a large scale project or a STREP project for specific tasks

[15] Specific Targeted Research Projects (STREP) are medium-sized research projects funded by the European Commission in the FP6 funding program

RESULTS

RESULTS

Assessing project success

As stated, the main goal of the KAPPA-Health study was to elucidate key factors accountable for the success of SMEs in research projects funded by the EU FP in the Health Theme. Accordingly, one of the key questions asked of SMEs during the survey was, whether they themselves would consider their participation in the FP-funded project a success. The answers were encouraging for the Framework Programme: 60% of the surveyed SMEs consider their participation a success and an additional 31% described their participation as at least partially successful.

Of course the self-assessment of success is rather subjective and does not necessarily indicate commercial success for the SMEs. In order to verify the self-assessment, additional questions about project results, and their impact on the company, were included in the survey. Project results were defined as direct products resulting from the project, new economic entities resulting from the project and changes in economic indicators such as turnover and the number of people employed. Results could include new products and processes such as molecules, diagnostic methods, prototypes but also publications, patents, and licenses. New economic entities could be spin-offs, new branches, subsidiaries or start-ups. In addition to these tangible project results, intangible results that are not as easy to quantify were also assessed. These include the potential to access new networks, internationalisation, new collaborations, and increased visibility.

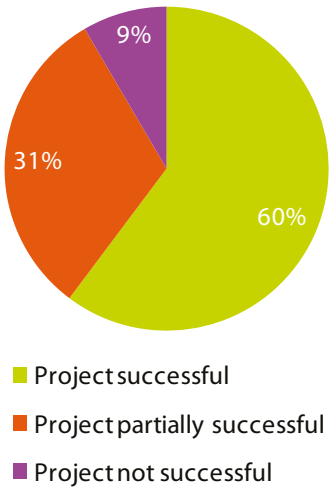


Figure 1: Self-assessment of project success by the surveyed SMEs (n=83)

Answers to questions related to project results in the survey generally corroborated the SME's self-assessment of success. The companies that claimed to have been successful achieved good and quantifiable results and new patents, products, processes or services often resulted directly from the project.

Additional reasons SMEs considered their project participation successful are presented in the following list in the SMEs' own words:

- "A new network was created, access was provided to expertise and facilities of other partners and an exchange of ideas and experience occurred"
- "International contacts, new collaborations and long term partnerships were developed"
- "New customers were identified"
- "Good channels were provided for dissemination of results"
- "New skills and knowledge were developed and expertise was extended"
- "New publications were issued"
- "Commercially exploitable new products or services were developed"
- "The results were sold to a major pharmaceutical company"
- "A new spin-off was formed"
- "New projects were initiated from the results"
- "Publicity was created for the company"
- "Interest was generated from investors"

Furthermore, 70% of the SMEs that answered that the project was only partially successful still developed a new product, process or service. It is therefore reasonable to assert that over 90% of all surveyed SMEs participated successfully in the FP research project.

The remaining 9% of surveyed SMEs that claimed that their project participation was not successful gave the following reasons:

- "Due to technical problems the expected results were not achieved"
- "Problems existed with the skill levels of some partners"
- "There was suboptimal collaboration between partners or too many partners with different goals"
- "Too much effort was needed for coordination instead of investment in R&D"
- "A marketable product was not achieved or the project was stopped by the EC for technical reasons"
- "Mistrust existed between partners regarding the exploitation of the results"
- "There was no efficient dissemination of the results"
- "The focus was too much on basic science rather than product development (uneven balance of academic and industrial partners in the consortium)"

Main Findings

The findings of the KAPPA-Health survey can be grouped into the following five categories:

- ***Strategy***
- ***Partnership***
- ***Commitment***
- ***Experience***
- ***Resources***

For each of these categories one or more success factor could be identified. Before a company enters into an FP project, its success factor position in each category should be evaluated. For this purpose, the KAPPA-Health consortium created an online tool for assessing a company's preparedness for successful participation in FP projects. (See www.kappa-health.org > predictive tool).

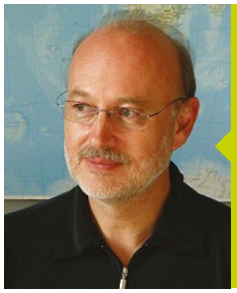
In the following pages, the key findings of the study are presented, divided into the above-mentioned five categories.

Strategy

In this report, strategy refers to the rationale that leads SMEs to enter EU FP projects as well as their role during the initiation and execution of the project.

The Role of SMEs in a FP project

SMEs are often not the project initiators (about 20% of the projects are initiated by SMEs). This fraction is somewhat higher among successful SMEs (33% of successful SMEs were among the project initiators and 19% were coordinators).



"We had access to otherwise restricted biological samples"

Prof Robert Zeillinger
Managing Director | ViennaLab Diagnostics GmbH

There is also a significant difference between the smaller Specific Targeted Research Projects (STREP) and the larger Integrated Projects (IP). SMEs were involved in project initiation in 25% of STREP and only 4% of IP projects.

The relatively low incidence of project initiation by SMEs can be linked to the role that SMEs normally play in the IP projects. In 60% of the projects, the SMEs had only limited, specific tasks to perform in the project and were asked to join the consortium either because of their specific skills or to comply with EC requirements regarding consortium composition. This invitation to take part in a project, sometimes even shortly before the deadline for project submission, is often seen by the SMEs as an opportunity for internationalisation and access to new infrastructures, expertise or samples, and is difficult to refuse.

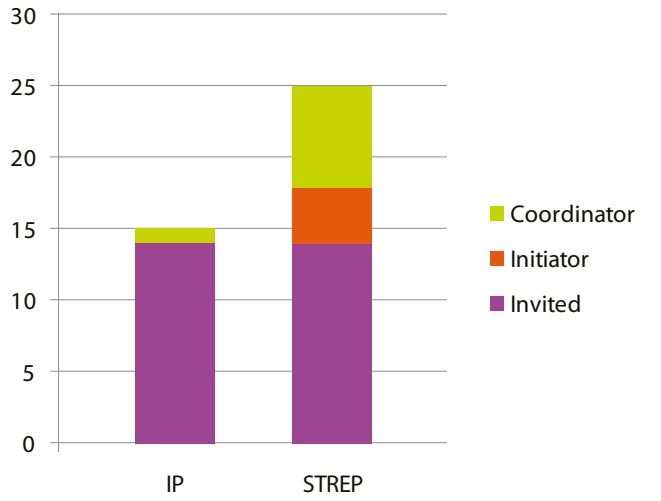


Figure 2: Role of the SME by project type (n=43)

Overall, only 7% of SMEs surveyed acted as project coordinators (almost all coordinating STREP projects and only one coordinating an IP project). All of the coordinators, except one, considered their project successful. 19% of all successful SMEs were the coordinator of the project.

Alignment with core activities of the SME

75% of SMEs reported that the project was aligned with their core activity. 68% of these SMEs considered that their project was a success versus only 38% of SMEs involved in a project not directly aligned with their core activity. Often the main result was simply the generation of new knowledge. Nevertheless sometimes this led to a success story.

Definition of the exploitation plan

In 66% of the projects the exploitation plan was well defined at the start of the project. The exploitation plan was well defined in 80% of successful projects and in 50% of the other projects, which clearly highlights that a well defined exploitation plan is an important aspect of project success. However, in defining the exploitation plan, SMEs often reported difficulties in defending their interests in front of large industrial partners and in advocating exploitation aspects in an academic consortium. In particular, the time frames of SMEs and academic partners are often not aligned and this can block project progress.

Some projects can be a real success in terms of scientific and technical results but can turn out to be a failure for the SMEs in terms of intellectual property rights (IPR) and exploitation if no agreement with the other partners exists. FP projects seem to be preferred to other programmes such as the Innovative Medicines Initiative (IMI) because the IPR rules are well defined in the contract. The IMI programme also carries a certain added risk for SMEs since they are collaborating with large pharmaceutical companies.

If a project is of high strategic importance for the company, external investors may have concerns about EU project participation because of the intellectual property issues raised by belonging to a consortium.

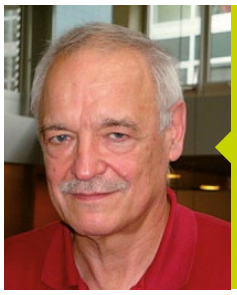
"A new service, which was substantially supported by the new knowledge gained through the EU project DecVac, has been installed within the company Geneart"

Dr Frank Notka
R&D Manager | Geneart

Partnership

Pre-existing collaboration with partners

Pre-existing contacts with at least some of the partners in the consortium is an important aspect of success. Overall, 64% of the SMEs had previous collaboration with one or several partners. This is true both for SMEs initiating projects as well as for SMEs that were invited to join the consortium. When an SME initiates a project, it typically does so together with a core group of academic partners they are used to work with. When an SME is invited to a consortium, it is often asked to join by an organisation they are used to collaborate with.



"Through the participation in the EU project a complementary successful merger with another SME business partner was effectuated"

Prof Hans-Peter Lipp
Founder and CSO | NewBehavior AG

In successful projects, 71% of SMEs had previous collaboration with one or several partners versus only 43% of SMEs in non successful projects.

Existing contacts should however never be the sole criterion for entering into a project. In our sample for example, one SME had a bad experience during a project specifically because it was coordinated by a friend.

"Participating in FP6/7 projects and collaborating with most competent partners allowed us to create Intellectual Property in the field of poverty related diseases"

Prof György Kéri
CEO & CSO | Vichem Chemie Research

To increase the chances of project success, partners must be well recognised in their field and generally should have as much experience in EU projects as possible. The only limit here might be that a partner involved in too many projects may have problems following several projects at the same time.

Small is beautiful

The majority of the surveyed SMEs participated in the smaller STREP projects (approx. 2.5 STREP projects for every IP project). Even if the level of success is similar for both types of projects, SMEs consider that the administrative and management effort is more cumbersome in large IP projects.

"A well structured and organised project leads to good results"

Dr Dietmar Katinger
Business Development | Polymun Scientific GmbH

For SMEs, efficient communication between partners is key. The participation of too many partners prevents efficient decision making and makes it difficult to stay on track. In addition, poor cooperation from some partners can slow down the project and even block it completely if other partners are relying on their results to complete their tasks. For this reason, well-thought project structure and task allocation is very important. To ensure quality in this area, the SME coordinators surveyed were prone to rely on external support for project preparation (6 out of the 8 coordinators interviewed had obtained outside assistance).

Project administration and management

Only 20% of IP projects and 15% of STREP projects encountered real management problems. Reported problems were usually linked to communication and cooperation between partners, communication with the EC and administrative burden. Some reported delays in reports approval and payments reduction for the whole consortium due to failure of only one partner.

Nevertheless, participation in large projects need to be closely considered by SMEs on a strategic point of view. The risk is that the SME participation could be marginalised in large project led by academic partners. On the other hand, collaboration with high recognised research organisations and Universities might bring recognition and trust to SMEs participating in the project. In this case they should build on the value of the consortium and evaluate the experience and objectives set up by the project coordinator and align them with their own business perspectives.

We observed that the most successful SMEs in large IP projects are those who were assigned a specific role linked to their core competencies and could benefit form their contribution and pursue their collaboration with some partners further to their participation in the project.

Support in project preparation

38% of the projects were supported for project preparation either by consultants or intermediaries (NCPs, Clusters, Universities support structures, etc..) 63% of SME project initiators or coordinators were supported by professional advisers for project preparation. In general SMEs initiated more often STREP than IP projects.

The involvement of external support services in project preparation and management is become more frequent as more SMEs have an active role (as project initiators or coordinators) in FP6 and FP7 projects.

Commitment

Company leadership

Generally, SMEs have more responsibilities in STREP projects rather than in IP projects. More SMEs acted as Work Package[16] leaders in STREP projects (52%) than in IP projects (36%). In IP projects SMEs primarily participated in specific tasks or as end users.

Most successful SMEs pointed out that the internal project leader must have the support of the company management team during the entire project, particularly if the project is not aligned with the core activity of the company. This prevents getting caught up in everyday activities and losing contact with the project, a common danger for SMEs that tend to be more medium term oriented than larger companies. If this happens, often no interesting results originate from the project apart from some new knowledge and fewer future collaborations result.

"The PortFastFlu project is very strategic for us. A specific management structure has been set up inside the project and inside the company. Several bilateral technical meetings are organised to keep all partners on board"

Dr Claude Weisbuch
Co-founder &chief scientist | Genewave

[16] In project management, a work package is a subset of a project that can be assigned to a specific party for execution.

In successful companies, the project was overseen by the same person throughout the whole duration. Participation at all consortium meetings was mentioned as an important factor for staying on track. When intellectual property rights were under discussion, the involvement of not only the project leader but key people from the management team was often necessary. In the most successful projects, CEOs were directly involved in the project follow-up.

Experience

Overall, FP-experienced SMEs are more successful in their project participation. 41% of SMEs participating in EC funded projects for the first time describe their project participation as successful in comparison to almost 70% of SMEs that have previous project experience.

The first project is often the most difficult one for SMEs. First-timers, in particular, report difficulties in adapting to the EC requirements in terms of reporting but also in understanding how a collaborative project works. There appears to be a learning process to optimising project participation.

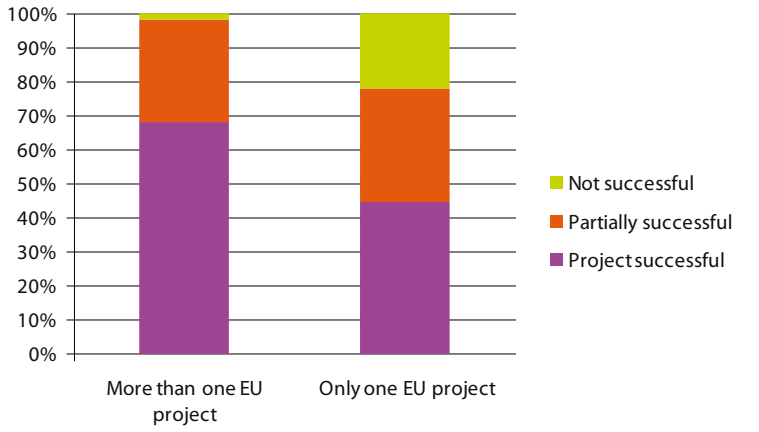


Figure 3: FP experience as a success factor

Some SMEs suggested that previous participation in national projects is often a necessary first step before entering EU projects.

According to our study, the management structure of the company or the backgrounds of individual managers did not impact success in the project. Success was rather linked to the entrepreneurial nature of managers and their commitment in the project.

"The APOPIS project helped Cellzome to continue its work on a Parkinson's disease drug discovery project"

Dr Gerard Drewes
Vice President of Discovery Research | Cellzome

Well developed SMEs fared better in our survey than their younger counterparts. Only 30% of all the SMEs surveyed were over 10 years old but this number increases to 60% if only successful SMEs are looked at. While SMEs younger than 5 years represented 8% of our survey, none were among those considered successful in their project participation. SMEs that acted as project coordinators were also generally more developed and were no longer located in techno parks or business incubators as is the case for 50% of the SMEs interviewed.

"An EU Project is the best way to realize risky project ideas"

Dr Bernd Mayer
Founding and Managing Partner | emergentec biodevelopment GmbH

Resources

84% of the interviewed SMEs indicated that without EC funding they would not have been able to conduct the research they did within the project. Some SMEs may have had the opportunity to fund some of the research themselves but for majority, particularly for the project coordinators, the EC money was essential for the project.

Sources of co-financing

65% of successful SMEs were already generating regular revenues from sales which enabled them to fund the portion of the project that was not funded by the EC. The lack of co-financing options might be one of the reasons very young SMEs are not among the most successful companies.

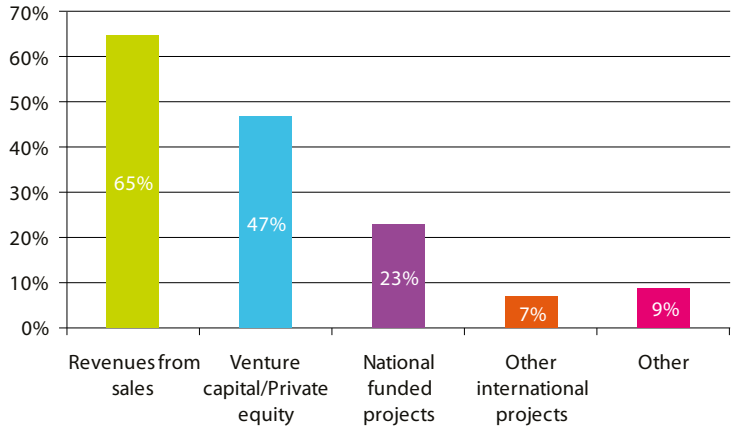


Figure 4: Funding sources used by SMEs to supplement EC project funding

It is clear that SMEs must have enough financial resources to co-fund the project and must be aware that final payments can be delayed after the end of the project. EU money is not intended for funding entire companies but for funding specific research projects; therefore, a contribution is expected from the SMEs. We observed that combining internal and external private funds slightly increased the chances of success for the project.

The FP7 funding rate of 75% was considered a big improvement from FP6 where reimbursement of eligible costs was allowed only up to 50%.

Human resources

In addition to the previously mentioned commitment, sufficient human resources are necessary to carry out a successful project without adversely impacting daily activities. This may be one reason SMEs with less than 10 employees represent only 25% of the successful companies.

56% of the successful companies hired a person specifically for the project (75% for IP projects and 52% for STREP) and 78% of these SMEs maintained the job after the end of the project (100% for STREP).

Half of the SMEs surveyed are based in techno parks or business incubators and half of these are spin-offs from universities and can often still benefit from university or hospital facilities. This is seen as an added value for project participation.

IMPACT ON SMEs

IMPACT ON SMES

Impact on knowledge gained

When analysing the results of our study, it must be considered that our survey was conducted quite soon after the termination of the FP research project for most participating companies. At this stage, the results obtained by the SMEs had already led to exploitation for 33% of the SMEs and a further 37% expected to exploit the results in the short term.

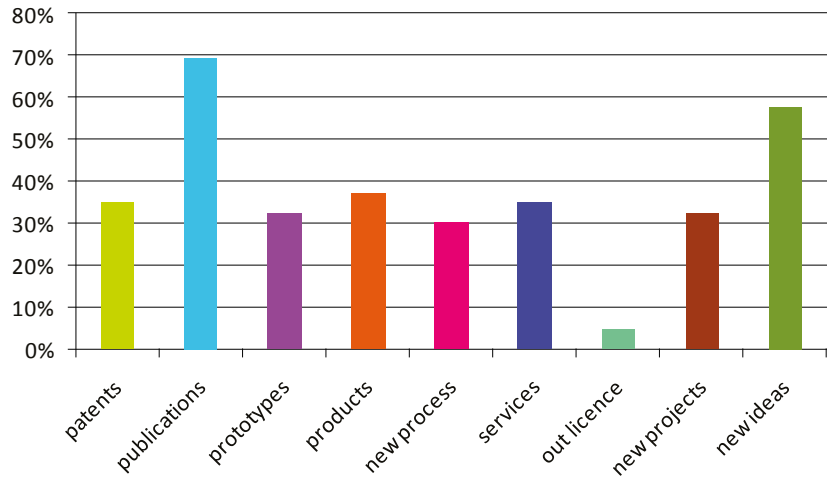


Figure 5: Results obtained by SMEs

As FP projects cover the whole spectrum of R&D activities, the outputs can be extremely diverse, ranging from the generation of new knowledge to a patented prototype ready for commercialisation. For most SMEs, the short-term objective of the research activity conducted in FP projects is to generate new knowledge through scientific findings. This survey indeed shows that almost all SMEs obtained at least new knowledge from their participation (87% of the surveyed SMEs stated that it was their first result).

However, compared to academic researchers that participate in FP projects, whose scientific findings are usually published in peer-reviewed journals, for SMEs, publication of the results obtained in their FP participation is not the first objective. Nonetheless, approximately half of all the surveyed SMEs jointly submitted publications in scientific journals and this rate reaches 70% for the successful, interviewed SMEs. 35% of the successful SMEs also made a new patent application.

Impact on employment and employee skills

SMEs were asked to evaluate the effect their FP project participation had on the number of people employed, the development of employee skills, employee motivation and productivity. Nearly 80% of the SMEs stated that participation in an FP project had significantly increased their employee's skill level in areas such as project and people management, collaboration with other professions or cultures and technical proficiency.

45% of the SMEs surveyed reported that the number of people employed in the company increased as a consequence of the project. This rate was even higher (56%) for successful SMEs. Around 65% of SMEs surveyed believed that the project positively affected their employee's motivation.

"The EU project FluDrugStrategy has resulted in a promising pathway for the development of a new antiviral against influenza"

Dr Heather Marshall-Heyman
Chief Program Officer | Vironova

"Through the participation in the EU project ReProTect, a patent application was achieved"

Dr Markus Bucher
Project Manager | Proteo Sys

Impact on commercial return and turnover

While commercial return is expected as a result of participating in the project by 52% of the SMEs (Figure 8) only 28% of the SMEs interviewed declared that they had actually implemented the exploitation of the results generated during the project, at the time of the interview.

Nevertheless 38% of the successful SMEs that we interviewed observed an increase of their turnover after project completion as a consequence of their involvement in the EU FP research project and especially those who were project coordinators.

"The EU project CAPPELLA allowed us to further advance our genetic chemistry platform towards discovery of novel diverse compounds with anti-cancer effects, while at the same time serving as a fantastic window to expose our innovative technologies to research institutes and companies across Europe"

Dr Neil Goldsmith
Managing Director & CEO | Evolva

There is a clear correlation between the age of the SME and the company turnover (7). It is worth to note that in the beginning of their existence, young biotech SMEs invest proportionally more in research than they are able to generate as turnover. Thus, it is not surprising that higher turnovers were found in SMEs older than 10 years.

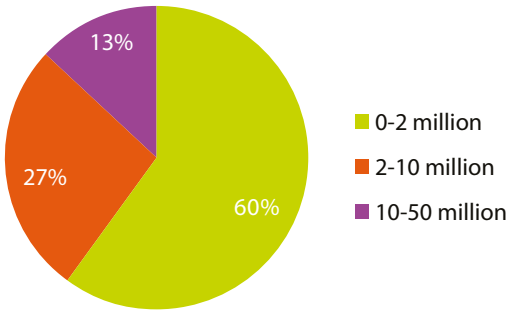


Figure 6: Distribution of surveyed SMEs by turnover in € (n=83)

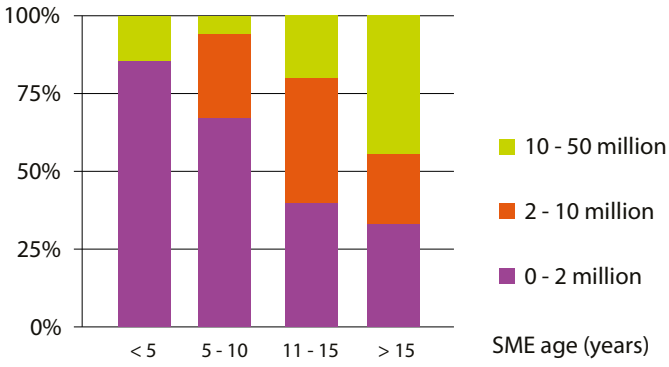


Figure 7: Turnover (€) vs. company age in the surveyed SMEs(n=83)

"Our project became a success because we, as a small company, secured the market orientation throughout all phases of the project"

Dr Antje Plaschke-Schluetter
Business Developer, Head of Application | Molecular Machines & Industries AG

Impact on innovation process

While some SMEs expected and successfully managed to increase their turnover following an FP project, it appears that a majority of SMEs are not participating in FP projects with a perspective to boost their turnover, at least directly.

Some companies explained that results generated during their FP participation were actually integrated in their innovation process without generating direct marketable products or services.

Indeed 26% of surveyed SMEs declared an increase of productivity after their participation in FP researsh project.

Even if according to another study, only 5-10% of all FP projects - although oriented towards applied research - lead directly to commercial products and services, industrial and scientific processes or new tools, machines and infrastructures within one to two years of completion[17], many projects contribute to the subsequent production of products, processes or services years later, through a multitude of indirect routes and after being complemented by the results of several other national or international research projects.

80% of FP participating SMEs need to pursue their R&D efforts and to develop proof of concept after a project termination (Figure 8).

It is likely that SMEs that are experiencing their first participation in a FP project are not able to evaluate the commercial exploitation of project outputs to their full extent.

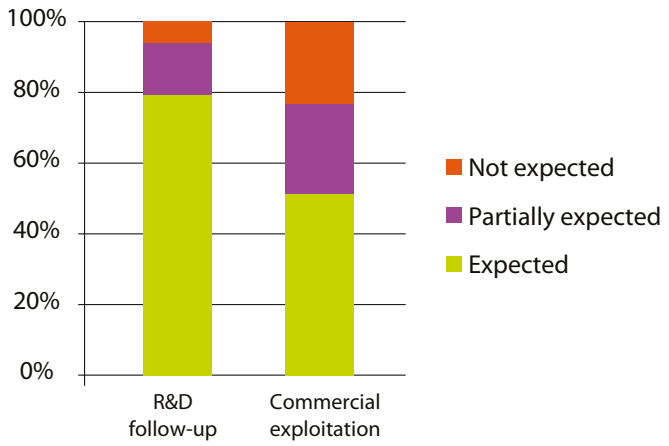


Figure 8: SMEs expecting R&D follow-up and commercial return as a result of the project (n=83)

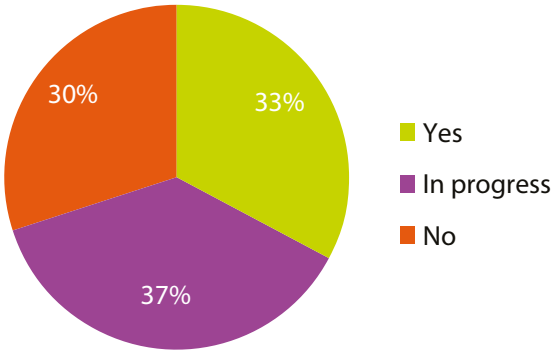


Figure 9: Implementation of results generated in the projects in the SMEs innovation process (n=83)

"Participation in the EU project INVITROHEART raised the company's recognition and enabled establishment of new contacts and collaborations"

Dr Reiner Claß
Head Toxicology & Preclinical Development | Pharmacelsus

"Being involved in the EU project Genostem provided us a good opportunity to work more rapidly, to have scientific discussions and identify potential customers within the consortium"

Dr Jean-Pierre Mouscadet
Business developer | AbCys

[17] EURAB, *"EURAB Recommandations on Ex Post Impact Assessment"*, EURAB Note 07.015, pp. 4–5, 2007

Impact on international collaboration

One of the outcomes from EU project participation, often valued as the most important by SMEs, was the large number of collaborations that continued after the project.

69% of SMEs continued to pursue collaborations related to research activities and 29% continued commercial collaborations. Only 7% of SMEs reported not being able to further their collaborations as a result of their participation in an FP project.

The willingness of the surveyed SMEs to participate in new collaborative projects was overall very high.

Only one of the SMEs surveyed stated that they did not wish to continue to participate in collaborative projects.

The majority (79%) of SMEs were ready for a new EU project and 12% were not sure. In general, EU projects were preferred to national and regional projects for several reasons including that they offer the potential to develop cross-border collaborations.

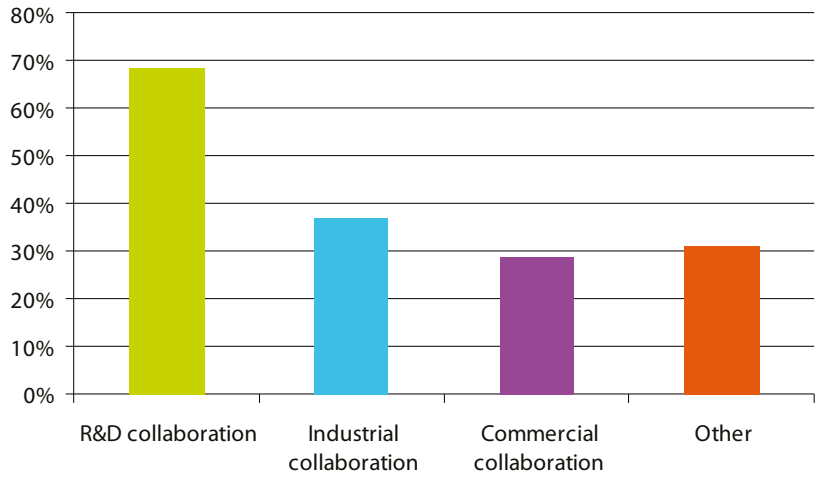


Figure 10: Continued collaboration as a result of FP project participation

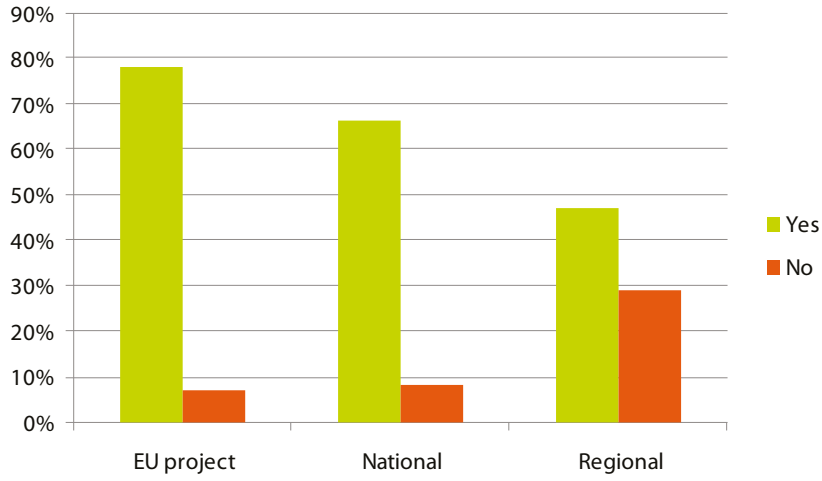


Figure 11: Intention of FP experienced SMEs to participate in future research projects at the EU, National or regional level

Impact on company visibility and recognition

Another outcome of EU project participation, that has been previously reported[18], was an increase in company visibility and recognition. Nearly 80% of surveyed SMEs indeed stated that their participation in an FP project increased company visibility and recognition, and 90% of the SMEs were able to develop new collaborations as a result of participating in an FP project.

Although it is difficult to measure this outcome, visibility and recognition are widely regarded as an important factor for company success, as knowledge of a company's business can drive growth. As a result, companies often devote a significant portion of their time and resources to advertising and networking activities. Participation in EU FP clearly fits as part of this strategy as it improves the SME's visibility on an international scale. By participating in FP projects, SMEs gain international visibility, without exerting special effort, through the project website, papers, leaflets, posters, handouts, presentations, and seminars which reach potential collaborators and clients. Thus, EU projects are important channels for building the international image of the company and broadening their market, especially in Europe. Participation in EU projects brings the SMEs into new, international networks and sets them in contact with prestigious research institutions and experienced researchers around Europe and the world. Obtaining good results and successful task execution within the project bring further external recognition.

By participating in a project as a partner, previously "unknown" SMEs can demonstrate their capabilities in quickly developing new prototypes and further commercialising these into products. This, in combination with the benefit of establishing new valuable international networks in their field, is priceless for the SMEs.

[18] Uotila et al., "Finnish Participation in the EU Fifth Framework Programme and Beyond", Finnish Secretariat for EU R&D.

ANALYSIS AND KEY PERFORMANCE FACTORS

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Limitations and strengths of the study

The goal of this study was to elucidate the key factors related to successful SME participation in EU-funded research projects. The focus was on research-intensive SMEs in the life science and health sector. This sector has its own characteristics, for example, tight regulatory constraints, long development timelines and high investment needs that are not necessarily present in other sectors. Despite these potential characteristic differences, we believe that a large portion of the study results can be valid for SMEs in other industrial sectors.

Since an emphasis was placed on contacting SMEs that had recently finished their research projects, the study results are essentially an ex-post evaluation of SME participation in FP6 projects. However, it is expected that key findings regarding successful participation can be generalised and are equally relevant for FP7 and future Framework Programmes.

Although the limited number of SMEs in the sample does not allow for statistically robust analysis, the SMEs surveyed nevertheless represent a considerable fraction of all research-intensive SMEs that participated in Life Science and Health projects under FP6. The findings of this report therefore truly represent the voice of biomedical SMEs and their view of their FP project participation.

Identified common patterns among the SMEs provided the basis for filtering out the key success factors. An initial list of potential success factors was presented to the interviewed companies and they were asked to evaluate these factors by relevance to project success. The ten highest ranked factors were validated by consultation with several stakeholders including investors, SME support organizations and consultants. In general, the stakeholders confirmed the relevance and importance of the identified ten key success factors. Their particular views on SME participation are described in the following paragraphs.

Views of private investors

Opinions of investors are mixed regarding the reward versus the effort of competing for EU money; however, many believe that any source of public funding and grants is a plus. The main concerns among investors are the issues surrounding IPR when companies enter into a consortium. The EU review process was not generally seen as adding credibility to companies receiving EU funding in the eyes of private investors; however if the funding was used to further a project to a stage attractive to investors this was viewed favourably.

In general, at the moment, most investors are neutral regarding the benefits and drawbacks of accessing EU funding and FP research project participation. The main focus for investing remains the quality of the management team, product pipeline, and technology platform and the potential market value.

An important factor that investors would consider, when investing in a company that is involved in an EU project, is whether the project plan matches the business plan. This opinion of investors greatly supports our first key success factor that the project must be in-line with the company's core business. In addition, the investors' views support the success factor that recommends SMEs have a strong basis of trust with partners but nevertheless make sure the IPR issues are properly addressed in the Consortium Agreement.

Views of National Contact Points (NCPs)

The network of National Contact Points[19] is the main structure to provide guidance, practical information and assistance on all aspects of participation in FPs. NCPs are regionally based and deliver personalised support on site and in potential applicants' own languages. The NCP system is based on collaboration and motivation of national organisations that reflect the specific working traditions and methodologies of individual countries. They represent a wide variety of organisational behaviours, from highly centralised to decentralised networks, and a number of very different actors, from ministries to universities, research centres, special agencies and private consulting companies.

Those NCPs contacted by the KAPPA-Health project agreed that the success factors identified during the project were both important and relevant although opinions differed as to the prioritisation. The NCPs generally stressed the importance of trust among partners, in particular related to issues surrounding patenting and intellectual property rights. They also highlighted the necessity for SMEs to comply with the legal and financial requirements of the European Commission. They also recommend that SMEs make sure they have adequate support (internal or external) on administrative issues such as accounting and reporting.

[19] Cordis, National Contact Points network, http://cordis.europa.eu > Funding > Get support

Views of the Enterprise Europe Network (EEN)

The EEN[20] helps small businesses make the most of the European marketplace. Working through local business organisations, the EEN helps SMEs to develop successful businesses in new markets, source or license new technologies and access EU financing and EU funding.

The KAPPA-Health project results were presented and discussed with the EEN at different venues. The Healthcare Sector Group of the EEN was asked to comment on the ten success factors as they are familiar with the challenges of biomedical SMEs. The EEN representatives made the following comments:

"*The enterprise Europe Network Sector Group Health Group does agree with the findings of the project. Still, the issue of exploitation strategies is of much concern. Indeed, Intellectual Property Rights in European projects need to be dealt with cautiously. The management and protection of research results should be clearly defined in the consortium agreement to avoid a default regime and consequently hamper the introduction of new solutions and products into the market. Furthermore, SME's should follow mid and long term research strategies congruent with their own strategic interests to avoid unfavourable scenarios where academia and industry follow diametrically opposed interests.*"

Mr Hicham Abghay, Chairperson Healthcare Sector Group, Enterprise Europe Network, Steinbeis-Europa-Zentrum

DO's and DON'Ts of successful FP project participation for SMEs

Based on SMEs interviews and discussions with stakeholders, we have consolidated the success factors elucidated from the project into a list of recommendations. We call these recommendations the "**KAPPA performance factors**" (KPF) for successful participation of SMEs in EU-funded projects

The following list presents the final key success factors identified by the KAPPA-Health project, formulated in the form of recommendations for SMEs who consider participating in projects funded by the European Framework Programme for Research and Development.

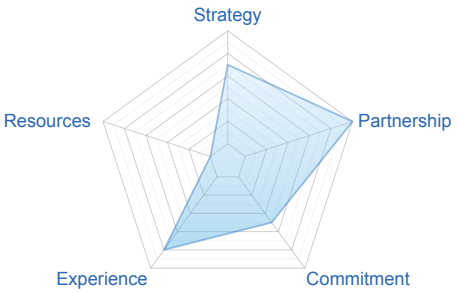
THE KAPPA-HEALTH TEN KEY PERFORMANCE FACTORS

An SME that is successful in EU projects should:

- Consider applying for EU funding only for projects in line with the core activity of the company.
- Enter the project with partners that are extremely competent in their field, are committed to the project and respect the business interests of the SME.
- Build on existing networks and ensure that the consortium is made up of partners that have had previous collaboration and can align their interests.
- Ensure the coordinator has experience, a track record of reliability, positive references and understands and supports the business interests and market orientation of SMEs.
- Contribute to a clear, well structured and thought-out project implementation plan.
- Expect to be persistent, committed and take on leadership roles throughout the project.
- Make sure the company is represented in project meetings by key personnel, i.e. people with decision making power, who are clear about the company's objectives. Be prepared to request participation of key personnel from partners.
- Ensure communication channels are well established and a regular communication schedule is set up in advance and enforced by the coordinator throughout the project.
- Have a strong basis of trust with partners, but nevertheless make sure that issues of intellectual property rights are properly taken care of in the consortium agreement.
- Anticipate possible delays in payment and have financing available to bridge the gap and supplement EU funding.

[20] www.enterprise-europe-network.ec.europa.eu

The KAPPA-Health Predictive tool



The KAPPA-Health predictive tool

The KAPPA-Health **Predictive tool** has been designed on the basis of the 10 Key Performance Factors (KPF) for a successful participation of SMEs in FP6/7. It aims at helping SMEs to predict at a glance their opportunities to enter in a successful FP project.

After answering a series of questions, the SME receives a score regarding its approach on critical aspects such as strategy, partnership, commitment, experience and resources. The predictive tool intends to give to SMEs some recommendations to help them enter in and FP project with greater chance of success.

PREPARATIVE PHASE	PROPOSAL PHASE	PROJECT EXECUTION PHASE
Get Informed	**Stay informed**	
Get Prepared • Conduct a feasibility study • Be open to internationalization • Network actively	**Be prepared** • Network actively • Attend conferences, hold presentations and take part in training	
Choose a project • ONLY if it is of real interest to the company	**Concentrate on your business** • Accept tasks closely related to your company's core activities	**Stay Organised** • Keep your objectives • Follow your execution plan
Choose project partners • With matching technological and commercial interests • That are proactive and committed and have a proven track record • With a record of applying scientific results • That you will meet face to face	**Organise well** • Set objectives, goals & milestones • Define precise rules • Be involved in the project's governing board • Make a good exploitation plan • If possible, involve project administration experts	
Choose a coordinator • That is well known in the field • Has experience in EU FP • That is politically connected		

- ***Take care of IPR issues***
- ***Communicate internally & externally with partners, task leaders, coordinator & EC project officer***
- ***Seek additional funding. Do not rely solely on EC funds***

Figure 12: FP Do's and Don'ts as considered by SMEs with successful participation in FP projects

POLICY RECOMMENDATIONS

POLICY RECOMMENDATIONS

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In addition to input regarding the success factors presented in this report, the surveyed SMEs also gave feedbacks regarding areas for improvement which mainly address the conditions of the Framework Programme and its implementation through the projects.

This section first gives an overview of the KAPPA-Health outcomes and subsequently presents the views of stakeholders that were discussed during EC conferences and meetings with European associations representing Healthcare Bioindustry, Biomedical and Med-Tech sectors.

Improvements for EU project collaboration

Further to the success factors focused on SMEs, other findings from the survey address current practices in EU project collaboration and how they could be improved. Comments were directed at the European Commission who sets the framework for the funding programmes.

Call objectives: Companies suggest offering more open topics allowing SMEs and private industries to freely choose their topics and partners, or leaving call topics open throughout the whole duration of the programme. More frequent calls and evaluation cut-off dates would be preferred. The organization of match-making events appears to be a good way to match industry and academic interests and allow SMEs to become involved in project proposals at an early stage. These match-making events should be organised more frequently. Cordis and Fit for Health projects and partners databases should be more geared towards match-making.

Project selection: SMEs are discouraged by the low selection rate of projects. They have the feeling that evaluators distrust projects coordinated by SMEs. They expressed some mistrust concerning the partiality and competencies of the evaluators. More representatives of industry should be involved in the evaluation panels.

Consortium Agreements: It is clear that there is a gap and major difference between SMEs and academia in term of language, tools, objectives and expectations. For example, the negotiation of the consortium agreement can take time for academic partners while SMEs need rapid validation. SMEs do not feel strong enough to confront academic partners that are more inclined to publish instead of patenting. They would appreciate the support of the EC as mediators of IPR issues.

This problem is exacerbated when SMEs collaborate with large industrial partners. With regard to IPR considerations, small consortia are preferred as this reduces the number of problems. SMEs also suggested allowing the involvement of subcontractors.

Size of project: Small projects with less than 10 partners are preferred rather than large projects as they are easier to manage. SMEs recommend for the EC to finance a larger proportion of small sized projects.

Role of the SME: It was suggested to allow SMEs participate In FP as subcontractors in a more flexible and substantial way, for example, for companies delivering materials or providing services for clinical trials. This could provide an easier way to become involved in an initial project that could provide experience and lead to further involvement in projects as full partners.

Administrative procedures: It can take time to have reports approved and payments received. This endangers the resources of the SMEs and delays technical progress of the project.

Project officers: It was mentioned that some project officers need stronger scientific and technical expertise necessary to follow the projects and that too much energy is focused on administrative issues. More balanced control mechanisms to really follow the technical progress and less cumbersome administrative procedures would be appreciated.

Project reviewers: Surveyed SMEs mentioned that the expertise of the project reviewers was not always suitable for the project.

Reporting Process: Mastering the reporting process is difficult and time consuming. SMEs would appreciate a software tool or system that would help them maintain timesheets, task reports, costs incurred and expenditures. The use of average hourly rates and a simplification of the financial audits would be welcome. The support of external management companies is also well appreciated in large projects.

Coordinator: The expertise of the coordinator is crucial. The coordinator must have strong scientific and technical expertise as well as managerial skills. Special training sessions for coordinators, especially for SME coordinators, would be a good idea. Most SMEs are advised not to be the project coordinator due to the high management workload required. Nevertheless, some SMEs prefer the role of coordinator as it allows for better control of the project and carries a higher likelihood of achieving the expected results. When SMEs are project initiators they are often more successful but they have to be well prepared to be a leader.

Collaboration in the consortium: The problem of unequal contribution to the project with one or several partners not meeting expectations is often encountered in EU projects. The possibilities to use a shared management tool to monitor partners that do not deliver, and a system for imposing sanctions, are missing. In many cases the lack of contribution by one partner is compensated for by additional contributions from other partners, without additional funding, who do not want to see the project fail. This can be particularly detrimental to small consortia and can endanger the achievement of the objectives.

Contract amendments: The problem of unequal contribution by project partners is compounded by the long amendment process; it is not possible to easily or quickly replace or expel the defaulting partner. Furthermore, such a process often leads to changes to the "Description of Work". Flexibility should be improved by simplifying partnership modification and work plan organization according to project progress.

Orientation of Framework Programme topics with the market

Over the long term, many stakeholders believe a new approach is needed for the calls, which puts more emphasis on the market opportunity and product applicability instead of focusing on an interesting problem or a piece of research.

According to EuropaBio[21], a more coherent framework is needed which addresses all phases of the innovation process. FP7 could also be adapted with a scheme that ensures that the transition of successful projects to the next module is more automatic and the value of earlier investment is therefore captured and the development of new businesses is supported.

To ensure that research ideas have enough funding to reach the phase of commercialisation there is a need for increased funding in the pre-profit phases, for example, by supporting feasibility studies with 'exploratory awards' or 'innovation vouchers'. This way FPs could fill the gap between pre-competitive research and commercialisation of the end–products.

More calls directed at SMEs with improved levels of funding would be important. This would also mean that SMEs would be less dependent on including a big company to support the projects. Open deadlines and semi-annual evaluations would be preferred and would better fit the needs of SMEs.

Involvement of SMEs in the selection of topics and more administrative flexibility

The involvement of SMEs in the strategic planning of areas and themes of future calls should be increased to encourage their participation in FP projects. SMEs viewpoints could be represented via the National Association and/or national focal points of the Framework Programmes.

Many SMEs stressed that fundamental problems with the FP include the time needed for the approval process (from preparation of the proposal to final approval of the project) and delayed payments. These delays are often unacceptable for SMEs and hinder their participation. Although delayed payments are often caused by inexperienced coordinators, an overall lowering of the administrative burden could minimize this problem.

A better communication between coordinator, scientific and financial officers both at the EC and company levels would also help streamlining the administrative process.

There is also a need for clear rules of engagement regarding IPR transfer and transparent administrative procedures.

Training and support for coordinating SMEs

Overall, most stakeholders agree that workshops and seminars for new coordinators could largely diminish the problems of mismanaging. Workshops and seminars on legal and administrative procedures regarding IPR transfer would also be very helpful.

[21] EuropaBio is the European Association for Bioindustries .EuropaBio's mission is to promote an innovative and dynamic biotechnology-based industry in Europe. (www.europabio.org)

CONCLUSION

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Benefits of Public Funding

The healthcare biotechnology and medical technology sectors are essential to Europe's growth and prosperity. SMEs are an integral part of the healthcare industry and are responsible for numerous breakthroughs and innovations. EU FP projects are an excellent financing instrument for SMEs during the pre-market phase and public funding is a welcome addition to other sources of financing, such as existing business revenues and venture capital investment, as it stimulates R&D and the development of new products and prototypes.

In contrast to private investor funding, public funds allow SMEs stay independent of external decision makers and doesn't result in a dilution of company shares. With this in mind, it is not so surprising that 92% of SMEs participating in the KAPPA-Health study stated that their project was a complete or partial success. The belief that EU public funding is an important part of early stage research was reinforced during face-to-face interviews.

Outlook

The fact that SMEs play a vital role in research within Europe, and figure significantly in healthcare biotechnology and medical technology, is well known. These SMEs benefit from R&D programmes focussed on Health Themes and help to strengthen Europe's competitiveness in this sector.

EU-funded projects are well suited to promote networking and an exchange of knowledge between partners. Often, collaborations established during FP projects continue after the project is completed and lead to further business. The aim of producing a commercial product by the end of the project, however, is often not feasible in healthcare biotechnology and medical technology due to the large capital investments and long timelines required for clinical trials or proof of concepts.

In the previous Framework Programmes, research funding was distributed using a "one size fits all" model and the characteristics of individual sectors were not taken into account. In addition, funding was only provided for the project duration and did not consider pre-study phases or post-project phases. Such issues are currently under discussion for the preparation of the next Framework Programme where the focus will be much more on innovation. Efforts are being made to improve the efficiency of research and innovation funding at the national and EU level[22]. Different funding programmes and initiatives will be streamlined to cover the full innovation chain.

As an integral part of a prosperous economy and healthy population, R&D is a key factor for sustainable growth and an elevated quality of life. Faced with an aging population and strong competitive pressures from globalisation, Europe's future economic growth and jobs will have to come from innovation in products, services and business models. This is why innovation and R&D have been placed at the heart of the Europe 2020 strategy[23], the growth strategy of the EU for the next decade. As part of this strategy, key goals have been identified to make Europe a more competitive economical power, create more high quality jobs, and increase social cohesion.

With these goals in mind, Europe needs to create more impact from research and innovation funding. Although obstacles remain in transferring research outcomes from the laboratory through to development and commercialisation, the EU FP program is designed and intended to enable the EU to reach these goals.

"Simply attracting SMEs to enter into EU-funded research projects is not good enough. We have to make sure that the SMEs participate in these projects successfully. The KAPPA-Health consortium now delivers the basis and the tools to achieve this goal."

[22] Green Paper: "From challenges to opportunities: towards a common strategic framework for EU research and innovation funding", European Commission, Brussels, 9 February 2011
[23] European Commission, Innovation Union, http://ec.europa.eu/research >Research Policy > Innovation Union

ABOUT THE KAPPA-HEALTH PARTNERS

The KAPPA-Health project endeavours to assess and valorise the success of biomedical SMEs, which have received funds from FP6 and FP7 for research and technological development. The KAPPA-Health project includes six project partners of which five are SMEs. All partners posses complementary knowledge of EU Framework Programmes, managerial issues, financial markets and the challenges that SMEs face in achieving commercial success from research results and EU project participation.

Founded in 1990, **Euro Top** Cooperation Partners is a communications and project management consultancy specialising in e-management, scientific and commercial strategy development, corporate communications, web development, event organisation and the administration of international projects and consortia. Leader of the KAPPA-Health project, Euro Top has a strong background in Life Sciences as well as SME and innovation support in various projects under FP6 and 7 covering the themes of Health and European enterprises' competitiveness.

Alma provides services for Management and Funding of Innovation for large companies, SMEs, research organisations or Universities. Since 1993, the Innovation, Projects and Partnership Department is specialised in the setting up and the management of innovative collaborative projects at National and European levels. The company participated to the analysis of the Key Performance Factors for SMEs in FP projects and the investigation of sources of funding, both private and public, for SMEs in the life sciences area.

Beacon Tech Ltd. company focuses on providing innovation management services: obtaining R&D co-financing, locating strategic partners, coaching, management of innovation processes and technology audits. In the KAPPA-Health project Beacon Tech helps accelerating the process of bringing new products and services by European SMEs to the global market, by means of successfully exploiting public funds.

eurelations assists companies, universities and other organisations since 2005 in the initiation, acquisition and implementation of publicly funded projects, trains company and academic staff in R&D fundraising and also operates as project partner by administrating national and international research projects and organising and chairing consortia meetings and scientific conferences.

Steinbeis-Europa-Zentrum (SEZ) supports specifically SMEs and Universities to get involved in European RTD Projects and in trans-national technology transfer co-operations; regional key players to get involved in transnational networks; transnational initiatives of the region for good practice exchange in innovation issues and the implementation of foresight strategies in regional innovation.

Venture Valuation specialises in independent, third party assessment, valuation and monitoring of emerging high growth companies. Venture Valuation's global Life Sciences company database Biotechgate provides access to detailed company information which, combined with Venture Valuation's experience in the assessment of high growth companies and interest in the promotion of industry in the EU, enabled contribution to the KAPPA-Health initiative.

ACRONYMS AND ABBREVIATIONS

EEN	Enterprise Europe Network
FP	Framework Programme
ICT	Information and communication technologies
IMI	Innovative Medicines Initiative
IP	Integrated project
IPR	Intellectual property rights
KAPPA-Health	Key Performance Factor Assessment and Valorisation for Successful EU-FP Project Participation of Innovative SMEs in the area of Health research
LSH	Life Science and Health
NCP	National Contact Point
OECD	Organisation for Economic Co-operation and Development
R&D	Research and Development
SME	Small and Medium Enterprise[20]
STREP	Specific targeted research projects

[24] Enterprises qualify as micro, small and medium-sized enterprises (SMEs) if they fulfil the following criteria: < 250 employees, turnover ≤ €50 million turnover, balance sheet ≤ €43 million

www.kappa-health.org

The KAPPA-Health project endeavours to assess and showcase the success of biomedical SMEs, which have received funding from FP6 and FP7 for research and technological development. The KAPPA-Health project includes seven project partners of which five are also SMEs. All partners offer complementary knowledge and experience of EU Framework Programmes, managerial issues, financial markets and an awareness of the challenges that SMEs are facing in achieving commercial success through their research results.

Project partners:

Euro Top Cooperation Partners, Belgium (Coordinator)
www.eurotop.be, www.xtranet-isa.com

Alma Consulting Group, France
www.almacg.com

Beacon Tech Ltd, Israel
www.beacontech.eu

eurelations AG, Switzerland
www.eurelations.com

Steinbeis-Europa-Zentrum, Germany
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The KAPPA-Health project is funded by the European Commission

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