Fit for Health

Final report

Periods covered: 01/10/2010 – 31/03/2012 (1)
01/04/2012 – 30/09/2013 (2)

Final publishable summary

pictures

WP1 Supporting competence

Task 1.1 FP7 Step by Step guides and supplementary information material

FP7 in general

Financial Aspects in FP7

Certificates in FP7

There are three different certificates in FP7:

1. Certificate on the Financial Statements (CFS)
2. Certificate on the Methodology for Personnel and Indirect Costs (CoM)
3. Certificate on the Methodology for Average Personnel Costs (CoMAv)

The costs of the Certificates can be reimbursed under Management/Subcontracting.

A Certificate on Financial Statements (CFS) is mandatory for:

Every claim (interim or final – Form C) in the form of reimbursement of costs whenever the amount of the EU contribution is equal or superior to EUR 375,000 when accumulated with all previous payments for which a CFS has not been submitted.

Once a CFS is submitted, the threshold of EUR 375,000 applies again for subsequent EU contributions starting from zero.

Certificate on the Methodology (CoM) & Certificate on the Methodology for Average Personnel (CoMAv):

A Certificate on the Methodology (CoM) is optional for the 'big players' with multiple participations in FP7, a Certificate on the Methodology for Average Personnel Costs (CoMAv) is optional for participants using average rates.

TIP from an SME

BRIDGE is a FP7 project and one of the SME partners in the project, KSL Laboratories, shared their experiences: "At the end of the project, I have to provide a Certificate on Financial Statements of my expenses. Thanks to my project coordinator, he reminded me to keep every important document such as the Grant Agreement, Form Cs, timesheets, salary slips, receipts, accounting documents – your auditor will need them!" (KSL Laboratories, Turkey, participating in 'BRIDGE').

Payment Modalities:

The EU contribution consists of three parts, the pre-financing, the interim payment(s) and the final payment.

1. Pre-financing: is received by the coordinator within 45 days of entry into force of the Grant Agreement to ensure a positive cash-flow during the project duration. It is equal to 160% of the average EU funding per period for projects with more than 2 reporting periods OR equal to 60-80% of the total EU contribution for projects with 1 or 2 reporting periods. It remains the property of the EU until the final payment.

   The coordinator receives a net amount of the Pre-financing minus 5% of the maximum EU contribution which is directly transferred by the Commission to the Guarantee Fund.

2. Interim payment(s): The interim payment(s) correspond(s) to the accepted EU contribution and are paid after each reporting period. Limitation: pre-financing + interim payments may not exceed 90% of the total EU contribution (they hold back at least 10% for the final payment).

3. Final Payment: Equal to the difference between the accepted EU contributions minus the amounts already paid. It is limited to 10% of the maximum EU contribution and paid after approval of the final reports.

When transferring the final payment, the Commission also instructs the Guarantee Fund to pass the 5% to the Coordinator.

Check List:

- Get acquainted with the FP7 Grant Agreement (GA) and Annex II which includes the implementation of the project, financial provisions and IPR issues
- Read the Guide to financial issues, with special focus on the funding scheme to which you are applying
- Check if your budget will fall under CFS obligation
- Check the Audit Guide (Certificates issued by external auditors - Guidance notes for beneficiaries and auditors)
- Be in contact with the Health and/or Financial NCP of your country.

Relevant Links:

- http://cordis.europa.eu/fp7/find-doc_en.html
- http://cordis.europa.eu/fp7/calls-grantagreement_en.html#standard_ga
- ftp://ftp.cordis.europa.eu/pub/fp7/docs/financialguide_en.pdf
- ftp://ftp.cordis.europa.eu/pub/fp7/docs/guidelines-audit-certification_en.pdf
- www.finance-helpdesk.org

A network of 27 partners from 22 countries is there to assist you free of charge.

Project coordinator:
Ines Haberl, ines.haberl@ffg.at

Interested?
Contact your national expert now!

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FINANCIAL Aspects in FP7

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Evaluation and Grant Negotiation

Do you want to become an FP7 Evaluator?

Becoming an evaluator is an excellent opportunity to become familiar with programmes and projects, to network and receive information about the state-of-the-art in European Research. The registration process is generally open for all researchers and industry representatives. In order to be invited as an evaluator, you can register here:
https://cordis.europa.eu/emmfp7/index.cfm

TIP from an Evaluator

Gölderen Yanikkaya Demirel | Yeditepe University, Turkey

I was invited to Brussels eight times in order to evaluate STREP, INCO and Marie-Curie Actions' projects in the scope of FP6 and FP7. First of all, these experiences had increased my knowledge about project assessment, project writing, reading and evaluation. I had the opportunity to observe the evaluation process and contribute to the evaluation meetings. I also met many European scientists with whom I can collaborate in FP projects, and consequently my network in Europe increased because of these experts' panels.

Grant Negotiation and Grant Agreement (GA)

If a proposal is evaluated positively, the coordinator is invited to start negotiations with the Commission. He receives an **Invitation letter**, the Evaluation Summary Report (ESR) and the **Negotiation Mandate** listing the information needed by the negotiating parties.
The negotiation process is supported by an interactive online tool, called the **Negotiation Facility (NEF)**.
NEF is accessible via the Research Participant Portal (http://ec.europa.eu/research/participants/portal) where participants have to login via their ECAS accounts (European Commission Authentication System).
NEF helps to finalise the **Grant Agreement Preparation Forms (GPFs)** which provide the administrative information needed for concluding the Grant Agreement and the **Description of Work** (DoW, Annex 1 to the GA).

After the closure of negotiation, the Grant Agreement will be signed by the coordinator and the Commission. Subsequently, the other partners of the project formally join the Grant Agreement.

Consortium Agreement (CA)

This is an agreement between project partners. The European Commission is not involved. It includes all detailed administrative and management provisions necessary to carry out the research project but it cannot contradict or negate the provisions established by the Grant Agreement or the Rules for Participation. Consortium Agreements are mandatory for all projects financed through FP7 unless otherwise specified in the Call for proposals.

Once a proposal has successfully passed evaluation and is invited to grant negotiation, a Consortium Agreement can be prepared. It should be completed before signature of the Grant Agreement and each beneficiary should have entered into the CA when it accedes to the signed Grant Agreement.

The whole process, from the start of the evaluation through to the signing of the Grant Agreement by the European Commission, can last up to one year.

Checklist and links:

- Have a look at the negotiation guidance notes: ftp://ftp.cordis.europa.eu/pub/fp7/docs/negotiation_en.pdf
- Look at the checklist for Consortium Agreements: ftp://ftp.cordis.europa.eu/pub/fp7/docs/checklist_en.pdf
- Compare different Consortium Agreement models: http://www.funcia.org/otri/fp7/Comparacionde los-modelosdeacuerdodeconsorcio.pdf
- Learn more about evaluation procedures and criteria: ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-evrules_en.pdf
- Register yourself as an evaluator using the website: https://cordis.europa.eu/emmfp7/index.cfm
- Learn how to use NEF: http://212.68.215.215/display/Knowextwin/NEF+Documentation

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Project coordinator:
Ines Haberl, ines.haberl@ffg.at

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Evaluation & Grant Negotiation

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Management of an FP7 Project

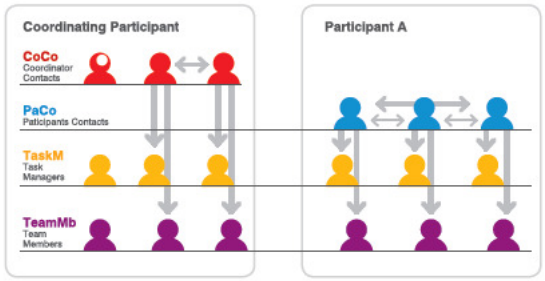
Intellectual Property Rights (IPR) & Valorization

Simplification in FP7

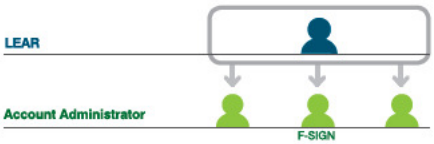
Horizon 2020

The Participant Portal

- Coordinator Contacts can nominate/ revoke other Coordinator Contacts, Task Managers and Team Members of the coordinating entity.
- Participant Contacts can nominate/revoke other Participant Contacts, Task Managers and Team Members of their own entity.



- The Legal Entity Appointed Representative (LEAR) can nominate Account Administrators of his/her own entity



Please note that only the key roles of the LEAR and Primary Coordinator Contact are defined/modified by the Commission. Except for the Primary Coordinator Contact and the LEAR, every role must be modified by the Participants.

Research and Innovation Participant Portal

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The Research & Innovation Participant Portal

The Research and Innovation Participant Portal is a web-based ground that offers stakeholders a unique entry point for the interactions with the European Commission (EC) or the Research Executive Agency (REA) in handling grant-related actions such as FP7 and future Horizon 2020 projects. The portal is based on single sign-on of the stakeholders via the European Commission Authentication Service (ECAS) and a role-based authorization (Identity and access management – IAM).

It provides access to legal entity registration, negotiation, amendments, financial and scientific reporting, expert services and brings homogeneity, transparency and better service integration for the grant management.

Roles and rights in the Participant Portal

Depending on the role in an organisation, a participant may have different access rights in different projects. It is possible to view organisation and project roles on the Participant Portal under the 'My Roles' tab. In addition it is possible to nominate new people by giving access to them.

Main changes in the Participant Portal

After February 2012, some changes occured in the portal. These changes offer more flexibility in the management of access rights and roles in the projects. While main principles such as ECAS account, 9-digit PIC number and the approval/modification of top roles by the EC/ REA remain as they were; there are a number of changes as well. These are listed below:

- Previously only one Coordinator Contact or Participant Contact could be nominated per organisation. Now, it is possible to nominate more than one Coordinator Contact or Participant Contact (max 5. per organisation).

  The newly invented Primary Coordinator Contact is the main contact for the European Commission.

- The scopes of scientific/administrative/legal representatives etc. have been transferred to new roles:

Scientific / financial representatives	Participant Contacts
Administrative/ legal representatives	Task Managers
NEW: Authorised signatories	F-SIGN

Transfer of roles

Primary Coordinator Contact: is the primary point of contact between the Commission and the consortium. The Primary Coordinator Contact has read and write access to all electronic tools, to the forms of his/her organisation and to the common forms of the consortium and can submit forms to the European Commission.

Coordinator Contacts: Coordinator contacts basically have the same rights as the Primary Coordinator Contact. The only difference is that the Primary Coordinator Contact is the only point of contact for the EC. All the previous scientific or financial representatives of the coordinating entity will automatically become Coordinator Contacts.

Participant Contacts: are nominated to represent the organisation within the consortium and all Participant Contacts have read/write access to their organisation's forms and read-only rights to certain common forms. They can submit forms to the Coordinator Contacts and can only be nominated/revoked by the Primary Coordinator Contact.

Task Managers: Can create, save and update forms of their organisation. There may be one or more Task Manager(s) per organisation.

Team Members: Have limited access rights: search, read-only. This could be a useful role e.g. for secretaries.

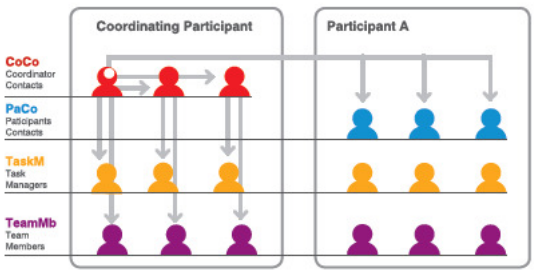
LEAR: is the legal entity appointed representative of an organisation. He/she is responsible for the updates of the organisation-related data, can request (online) the modification of such data, and upload supporting documents. He/she can access the list of roles/persons representing his/her organisation in projects and the project list of his/her organisation and can request to revoke users from roles within his/her organisation e.g. by asking a Coordinator Contact or a Participant Contact to revoke a role.

F-SIGN: The electronic-only transmission of financial statements (Form Cs) started on 1 January 2013. In this new process organisations have to identify online the persons authorised to sign Forms C. For this, a new role, the Financial Statement Authorised Signatory (F-SIGN) is introduced in the identity and access management (IAM) of the Participant Portal. F-SIGN can sign the Form Cs, submit to the Coordinator Contacts and has read/write access to the forms of his/her own organisation. The LEAR nominates the F-SIGNs.

Nomination process

With the changes in the portal, it is possible to give access to other colleagues or to revoke the rights of a person who left the organisation or project. The nomination roles of the people in the project/organisation are as follows:

- The Primary Coordinator Contact can nominate/revoke Coordinator Contacts, Task Managers and Team Members of the coordinating entity and Participant Contacts of other participating organisations.



Alternative Funding Opportunities for SMEs in Health Research

EUROSTARS

The Eurostars Programme is a European Joint Programme dedicated to R&D performing SMEs, co-funded by the European Communities and 33 EUREKA member countries. It aims to stimulate SMEs to lead international collaborative research and innovation projects by easing access to support and funding. It is fine-tuned to focus on the needs of SMEs, and specifically targets the development of new products, processes and services and the access to transnational and international markets.

The main participant of any Eurostars consortium must be an R&D SME in order to satisfy the Eurostars eligibility criteria. Usually consortia are set up with R&D SMEs, SMEs, Research Institutes and Universities. An average project consortium is composed of 3-4 participants from 2-3 countries involved in the programme. Duration of the projects are roughly 29 months with a total budget of 1,4 M€. The bottom-up approach gives the freedom to participants to launch their projects in any technological and market area.

For more information about the EUROSTARS programme please visit: **www.eurostars-eureka.eu**

Please note that the programmes mentioned above are not the complete list of funding opportunities for Health research. There are further funding possibilities like ERA-NET calls, Eurotransbio etc...

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Project coordinator: Ines Haberl, ines.haberl@ffg.at

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Health Programme 2008-2013 Together for Health

Health Programme DG SANCO

The second programme of community action in the field of Health 2008-2013 is the main instrument, the European Commission uses to implement the EU Health Strategy. It came into force on 1 January 2008 and is intended to complement, support and add value to the policies of the Member States and contribute to increase solidarity and prosperity in the European Union by protecting and promoting human health and safety and by improving public health.

The Health Programme 2008-2013 is managed by the European Commission (EC) with the assistance of the Executive Agency for Health and Consumers (EAHC). The total budget for the programme is 321,5 M€ and it is implemented by means of annual work plans which set out priority areas and the criteria for funding actions under the Programme. Participation is open to a wide range of organisations, including research institutes and universities, public authorities, NGO's and commercial firms.

The programme has three overarching objectives. It seeks to:

- improve citizens' health security,
- promote health and reduce health inequalities, increasing healthy life years and promoting healthy ageing,
- generate and disseminate health information and knowledge, exchanging knowledge and best practice on health issues.

For more information about the Health Programme please visit: **http://ec.europa.eu/health/programme/policy/index_en.htm**

EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP)

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a partnership of 14 EU countries, Switzerland and Norway, and 47 sub-Saharan African countries, which aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria, with a focus on phase II and III clinical trials in sub-Saharan Africa through a long-term partnership. EDCTP offers multicenter grants to support clinical trials, as well as networking and capacity building activities, in order to create a sustainable environment for conducting high-quality medical research in sub-Saharan Africa. The main EDCTP grant schemes are Integrated Projects, Senior Fellowships, Ethics, Member States Initiated projects and Networks of Excellence.

The current EDCTP programme will end in May 2015. It is anticipated that there will be an EDCTP II programme under Horizon 2020, the EU Framework Programme for Research and Innovation (2014 to 2020).

For more information about EDCTP please visit: http://**www.edctp.org/Home.162.0.html**

The Innovative Medicines Initiative (IMI)

The Innovative Medicines Initiative (IMI) is Europe's largest public-private partnership aiming to improve the drug development process by supporting a more efficient discovery and development of better and safer medicines for patients. IMI is a Joint Undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

With a 2 billion € budget, IMI supports collaborative research projects and builds networks of industrial and academic experts in Europe that will boost innovation in healthcare. Every year, IMI launches a new Call for proposals. Through the Calls and the consecutive selection process, IMI aims to support research activities that will speed up the discovery and development of safer and more effective medicines. The open and competitive Calls for project proposals focus on research topics in the areas of safety and efficacy, knowledge management and education and training. The research consortia participating in IMI projects consist of large biopharmaceutical companies that are members of EFPIA, and a variety of other partners, such as SMEs, patients' organisations, universities and other research organisations, hospitals, regulatory agencies or any other industrial partners.

For more information about IMI please visit: **www.imi.europa.eu/content/mission**

Task 1.4 National SME fora

WP2 Training SMEs & Academia: FP7 Newcomers and Applicants

Task 2.1 Trainings for “FP7 Newcomers”

Task 2.2 Trainings for “FP7 Applicants”

WP4 Enhancing cooperation of SMEs and Academia

Task 4.3 Partnering Events





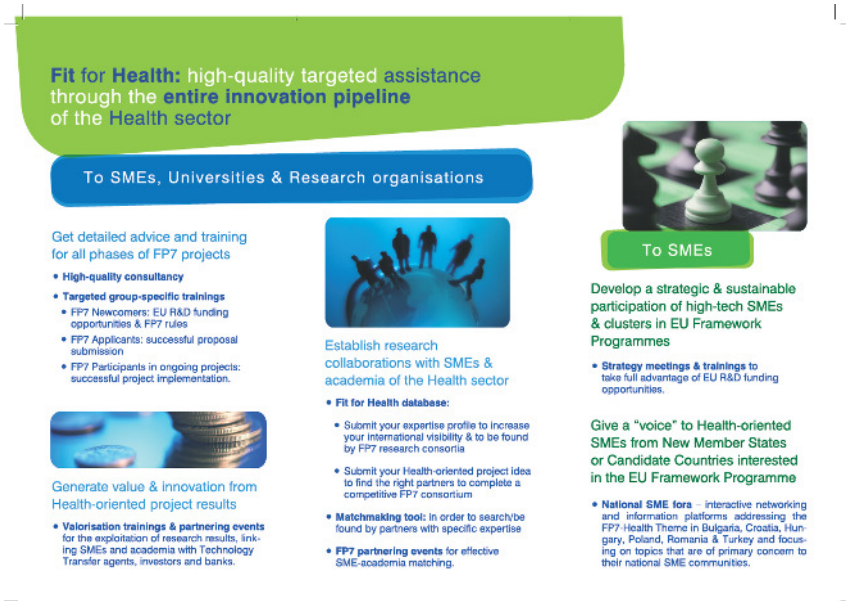

WP5 Innovation and Generating value

Task 5.2 Valorisation partnering events

WP6 Promotion and Networking

Task 6.1 *Fit for Health* website and PR material

Leaflet



Poster

Fit for Health

Supports SMEs & researchers
in Health-oriented FP7 projects
from the research idea to the exploitation of research results

Your best way for partners & projects in Health in FP7!






A network of **27 partners from 22 countries** is there to assist you free of charge!

High-level assistance offered through:

- **Targeted group-specific trainings** for all phases of FP7 projects
- **FP7 matchmaking assistance & events** to initiate research collaborations
- **Valorisation trainings & events** to close the knowledge gap between research results & marketable products/services
- **Strategy meetings & trainings** for high-tech SMEs and clusters to take full advantage of EU R&D funding
- **National SME fora** to give a voice to SMEs from NMS & ACC interested in the FP7-Health Theme.

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Roll UP


Fit for Health .eu
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Fit for Health
High-quality assistance to SMEs & researchers of the Health sector through the entire innovation pipeline
Targeted group-specific trainings for all phases of FP7 projects
FP7 matchmaking assistance & events to initiate research collaborations
Valorisation trainings & partnering events to close the knowledge gap between the R&D project results and the products/services ready for the market
Strategy meetings & trainings for high-tech SMEs and clusters to take full advantage of EU R&D funding
National SME fora to give a voice to SMEs from NMS & ACC interested in the FP7-Health Theme.
Your best way for partners & projects in Health in FP7!
A highly experienced network of 27 partners from 22 countries is there to assist you free of charge!

Example Success Story

FP7-Success story of EXPLORA SRL

THE GRAIL: Tissue in Host Engineering Guided Regeneration of Arterial Intimal Layer

Topic
HEALTH.2011.1.4-2 Tools, technologies and devices for application in regenerative medicine

Funding Scheme
Collaborative Project (Small or medium-scale focused research project)

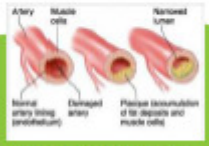
Project coordinator
EXPLORA SRL

Project Duration
January 2012– December 2016

The Tissue In Host Engineering Guided Regeneration of Arterial Intimal (THE GRAIL) project aims at designing and developing a bioactive and bioresorbable scaffold that locally regenerates intima growth after endovascular treatment of the obstructed arteries in patients with atherosclerosis.

EXPLORA SRL	*IT (SME)*
Universitair Medisch Centrum Utrecht	NL (UNI)
Universidad de Valladolid	ES (UNI)
Conic Vascular Technology	CH (SME)
Università degli Studi di Napoli Federico II	ITA (UNI)
University of Liverpool	UK (UNI)
Fundació Privada Institut de Bioingenieria de Catalunya	ES (RTD)
Donawa Lifesciences Consulting SRL	ITA (SME)
Technical Proteins Nanobiotechnology SL	ES (SME)

EXPLORA BIOTECH SRL is a privately owned Italian company established in 2006 at the Technological Park "Tecnopolo Tiburtino" in Rome by a pool of young researchers and the support from a French seed capital organization INVENT SaS.



interview

Please provide your feelings about the coordination of a project under FP7, and the collaboration between academia/SME during the life of the project?

Davide de Luorezia :(CEO of Explora Biotech)

"It is a great experience coordinating 7 teams of researchers with interdisciplinary skills and competence, it broaden my perspective on science and technology beyond my field of training. The cooperation between SME/Academia allows to couple cutting-edge research to a problem solving attitude that significantly speeds up the development process.

As a result of a project, did you get any product that could be potentially commercialized? Did you finally put it in the market?
If yes, what were the main difficulties?

Davide de Luorezia :(CEO of Explora Biotech)

"The project is currently running and preliminary results are encouraging. Our exploitation strategy foresees the setting up of a NewCo to further develop the THEGRAIL device up to clinical trials."

Regarding the next framework programme Horizon 2020, what are your future perspectives?

Davide de Luorezia :(CEO of Explora Biotech)

"FP grants were based on topic-centered calls which were instrumental to shape EU research strategy. I hope that H2020 will implement more open-topic calls (in close analogy to FET-OPEN) to nurture breakthrough idea alongside with small-size highly-focused translational project to effectively translate research and innovation into market."