ARIaT - Horizon 2020 Annotated Research and Innovation Actions Template

Innovation dimension in Horizon 2020 proposals:
Set of good practices to understand and write innovation related issues both in Research and Innovation Actions (RIA) and Innovation Actions (IA).

Health 2 Market
FROM HEALTH RESEARCH TO BUSINESS

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Introduction and Background

The '**ARIaT – Annotated Research & Innovation Actions Template**' is a guide aimed to assist applicants to the **Research and Innovation Actions and Innovation Actions** for the Horizon 2020 Framework Programme for 2014-2020 to better understand the requirements of the template and better write innovation related issues. It is provided for informational purposes only and it is targeting any project formulator and it reflects only the view of the authors.

This user's guide that has been produced as part of the Health-2-Market project (H2M), a coordination action funded by the European Commission that aims at developing the health researchers' entrepreneurial skills and knowledge to support the market exploitation of their research results. The authors of the ARIaT are experts dealing with Horizon 2020 proposals, innovation, exploitation of R&D results, and generally with entrepreneurship and business development on day-to-day basis. Their recommendations are indicated in the document as "**Expert recommendations**" and also include feedback collected from evaluators of H2020 proposals.

During the Health-2-Market three-years life cycle, these experts interacted, trained and consulted hundreds of participants who wanted to introduce their innovation to the market. This guide is largely based on the needs of the participants, as they emerged from these interactions.

The message we want to emphasise is also that a successful project proposal needs to speak out convincingly to a broad readership encompassing experts from a wide range of fields. While the scientific/technical soundness of a proposal is central to its ultimate success, it is also essential that the **challenges to be addressed, the opportunities** to be exploited, and the **results** to be achieved are clear and understandable to all readers, specifically to H2020 evaluators! Moreover, the linkage between results to be achieved and their relevance for European policy orientations should be clear, as well as the economic opportunities they will provide for citizens. This is why we started to work on this H2M product and we sincerely hope it will be a useful addition to your usual mindset when you are writing your project. The ARIaT template has been structured to guide project formulators in presenting information required especially by the criteria of **Excellence** (criterion 1) and **Impact** (criterion 2). It is meant to provide formulators with clear guidance to structure the **innovation aspects** contained in their proposals in such a way as to speak to both non specialist and specialist readership. We aspire it to be useful for everyone who wants to fill in a H2020 innovation related proposal.

Horizon 2020: a balanced approach between research and innovation

The Horizon 2020 Programme aims to ensure a balanced approach between research and innovation activities, more than in any previous Framework Programme. It is not only limited to the development of new products and services on the basis of scientific and technological discoveries, but also pays attention to other sources such as the use of existing technologies for new applications, incremental innovation, non-technological innovation (business model, design) and new ways of interaction with users, customers, or suppliers. The programme also puts a clear emphasis on the importance of achieving impact and innovation by encouraging collaboration between **researchers, industry and the citizen**.

Aim and content of ARIaT

The aim of the annotated template is then to highlight and emphasise the **innovation elements** that an excellent project application should contain.

The **Expert recommendations** and the **Examples** provided in the document are intended to help applicants when developing their own proposal by clarifying certain relevant points requested in the proposal template. These examples are not from a running or funded project and should not be followed blindly, but seen as illustrations of the expert recommendations. Moreover, for the sake of brevity, these examples are relatively shorter than in a typical H2020 proposal. They are meant to give you an idea of the topics that should be covered, but these topics should be described in greater detail in your proposal.

The three main criteria used to evaluate the **innovation aspects** of a project proposal for H2020 are:

- **Excellence** (criterion 1) assesses the extent to which the proposed solution is innovative compared to other products already developed or with respect to the problems that still do not have an adequate solution/response
- **Impact** (criterion 2) must demonstrate how the project will enhance innovation, with specific focus on the integration of new knowledge. It must also assess and quantify the competitiveness and growth of enterprises based on the project, in relation to environmental/industrial/social problems (such as level of commitment to Corporate Social Responsibility)
- **Implementation** (criterion 3) section must address, among other things, how the innovation will be managed. It is of particular relevance, as an effective innovation management allows the consortium to exploit new opportunities both outside and inside the project.

We have included in the Appendix 1 the criteria that each evaluator will use to evaluate your proposal.

The document's structure mirrors that of the proposal template for H2020. It focuses on and explains sections 1 and 2 (**Excellence and Impact**) with some mention also to criteria 3 (**Implementation**) and includes **examples** where appropriate.

As the H2M pool of experts has chosen to concentrate on Innovation aspects, we are providing recommendations for the relevant following sections only:

Section 1. Excellence (criterion 1), Subsection 1.1, 1.2, 1.3, 1.4;

Section 2. Impact (criterion 2), Subsections 2.1, 2.2 a-b;

Section 3. Implementation (criterion 3), Subsections 3.2, 3.3, 3.4.

We have included in the Appendix 2 an example of a **business plan executive summary**, in the Appendix 3 an example of **work packages** that addresses **dissemination and exploitation of results**, as well as **preparation of market authorisation and market access.**

How to read ARIaT?

The text of the original H2020 template appears in **black**.

Health-2-Market **Expert recommendations** appear in **grey** and are indicated by an **orange title**. These recommendations also include feedback collected from the evaluators of H2020 proposals.

Examples of suggested **good practices** are written in **blue** and indicated by a **bold** and **blue title**.

The ARIaT is limited to annotations to the provisions of the Horizon 2020 Research and Innovation Action calls. For a more general overview of how the Horizon 2020 grants work, see the Online Manual provided by the European Commission.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found on the Reference documents page of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

If you need help, you can also contact the H2020 National Contact Points of your Country.

"Commission lays out plans to manage low Horizon 2020 success rates"

Extracts from the article published on June 25, 2015, by SciencelBusiness:

"…The second main step planned by the Commission is to get stricter on rating the impact of a proposal for industrial technologies or a societal challenge.

Impact is one of the three criteria Horizon 2020 evaluators use to assess the quality of research proposals; the other two are excellence and the quality of implementation. In order to measure impact, several indicators are considered, such as, the capacity to innovate, the use of new knowledge, and contributions to the wider societal and economic impact. However, the key ones are those listed in the individual competitions themselves.

To be in with a shot of winning a grant, applicants will have to be sure that their expected impact is "clearly defined" and rigorous. ***Brendan Hawdon, Head of Horizon 2020 Policy in Smit's directorate-general, elaborated.*** *"It's all about the outcome," he said.*

An applicant should say clearly: "Here's what we want to come out of the project." For an innovation project, for instance, increasing the world's knowledge wouldn't count as a concrete impact. By contrast, in a transport project, creating safe devices for a car, which would halve the number of lives lost on the road, might be a better example. Other impacts might be on technical standards, or the economy, he said.

…Among other things, he said, there is a two-stage evaluation process: First on the 'excellence' of the science proposed, and second – evaluated by a different set of experts – on the societal, economic or other impacts. He said that exact system wouldn't work for the Commission, but the general focus on defining and assessing impact rigorously would. Of course, he added, "there is a risk that people will promise the moon. We have to be careful we aren't taken for a ride" by over-optimistic applicants, he said. As a result, he said, in Horizon 2020 extra emphasis will be given to the evaluators carefully reviewing the impact claims. "

http://sciencebusiness.net/news/77101/Commission-lays-out-plans-to-manage-low-Horizon-2020-success-rates

Proposal template (technical annex)

Research and Innovation actions
Innovation actions

Please follow the structure of this template when preparing your proposal. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the experts to make an effective assessment against the evaluation criteria. Sections 1, 2 and 3 each correspond to an evaluation criterion for a full proposal.

⚠ **First stage proposals:** In two-stage submission schemes, at the first stage you only need to complete the parts indicated by a bracket (i.e. }). These are in the cover page, and sections 1 and 2.

⚠ **Page limit:** For full proposals, the cover page, and sections 1, 2 and 3, together should not be longer than 70 pages. All tables in these sections must be included within this limit. The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).

The page limit for a first stage proposal is **15 (or 7 for SC 1 only) pages.**

If you attempt to upload a proposal longer than the specified limit, before the deadline you will receive an automatic warning, and will be advised to shorten and re-upload the proposal. After the deadline, any excess pages will be overprinted with a 'watermark', indicating to evaluators that these pages must be disregarded.

Please do not consider the page limit as a target! It is in your interest to keep your text as concise as possible, since experts rarely view unnecessarily long proposals in a positive light.

COVER PAGE

Title of Proposal

List of participants

Participant No *	Participant organisation name	Country
1 (Coordinator)		
2		
3		

* Please use the same participant numbering as that used in the administrative proposal forms.

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1. Excellence

Your proposal must address a work programme topic for this call for proposals.

⚠ ***This section of your proposal will be assessed only to the extent that it is relevant to that topic.***

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EXPERT RECOMMENDATIONS for **Section 1. Excellence**

The evaluators will check that the proposed activities in the proposal are in line with the call or topic. They will pay particular attention to key aspects of the award criteria (see **Appendix 1** for evaluation sub-criteria) and key elements to be provided as part of a proposal. Notably, under the "**Excellence**" criterion, to evaluate the extent to which the proposal:

Your H2020 project should not be presented as a scientific publication. Go straight to the point!

- has **innovation potential**, with particular reference to the corresponding section(s) in the proposal;
- presents focused and well-defined **objectives** in line with the call;
- targets **technological, logistical, and business** development requirements;
- is **relevant, feasible, sustainable** and represents a clear advance on the state of the art.

1.1 Objectives

Describe the specific objectives for the project[1], which should be clear, measurable, realistic and achievable within the duration of the project. Objectives should be consistent with the expected exploitation and impact of the project (see section 2).

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 1.1 Objectives**

Structure your project idea by defining and quantifying the objectives and highlighting your **"vision"** and **"mission". These two will clearly show what you want to achieve.** A vision is the representation of a desirable future conceived by your ability to identify opportunities in a given situation. On the other hand the mission defines what you do , or what you expect to do. It highlights the main **benefits** for the customers/end users/ patients/adopters, etc. and takes into consideration the values and expectations of the stakeholders. In this section 1.1, you may already introduce and highlight the **market opportunities** such as:

Highlight your mission, and how this will lead to your vision for a better world

[1] *The term 'project' used in this template equates to an 'action' in certain other Horizon 2020 documentation.*

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- new possibilities to better meet existing needs, offered by new technologies;
- current or expected regulations which might favour your product entrance into the market;
- societal changes including demography, social issues, way of life, ageing, new behaviours, that make your offering valuable etc.

...and explain how these might result to:

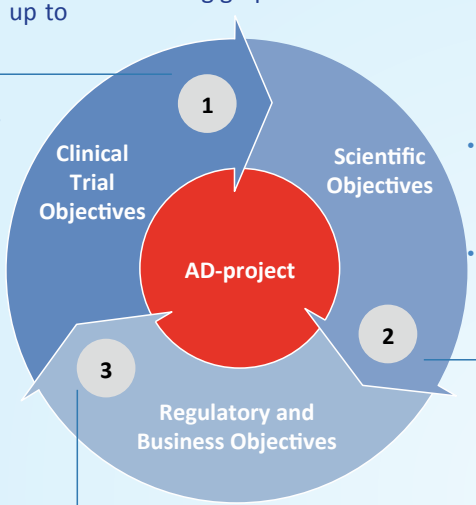
- larger demand for existing needs (e.g., the demand for services for the well-being of the elderly is likely to increase because European population is aging and life expectancy increasing);
- demand for new needs (e.g., more and more elderly people stay at home, despite facing medical conditions. This new and expanding market has different needs than hospitalised patients);
- demand for better solutions to existing needs (e.g., many elderly people facing medical conditions demand to be checked without disturbing their usual way of life).
- We suggest that you insert a graph or table which is visually summarizing your main objectives.

EXAMPLE: **"AD-Project"**

Alzheimer`s Disease (AD) is by far the most common dementia of later life and the leading cause of disability and death in the aged population. According to the World Health Organization it affects 36 million people worldwide[1]. Due to demographic changes an estimated number of 115 million people worldwide will be suffering from AD by 2050. Accordingly, current and especially future health care systems are facing tremendous costs. In 2010, the global economic impact of AD and other dementias was US$604 billion[2]. There is a tentative estimate of an 85% increase in costs to 2030. Despite its public health importance and recent advances in understanding its molecular pathology, no disease-modifying drug exists up to date that can halt or at least slow down the progression of AD. Present treatment strategies only provide minimal short-term benefit due to limited symptomatic treatment without targeting the underlying mechanism of AD.

Building on promising preclinical data, the 'AD-Project' proposal seeks to **advance the compound** as a treatment for AD by conducting a European Randomized Clinical Trial (RCT) for use in Early Alzheimer's Dementia (EAD). This RCT will be flanked with supplementary support activities in order **to ensure** its smooth performance, underpin the efficacy of the pharmacological treatment, and **plan** ahead and ensure Marketing Authorisation as well as reimbursement at an early stage of the product life cycle. The overarching purpose of these combined activities is **to bring to the market a safe, effective causal treatment for elderly individuals suffering from AD.**

In order to realise the above presented **vision**, the AD-Project project has a three-fold focus, as it appears in the following graph:



- To validate the putative disease modifying effects on cognition
- To underpin the theory that the compound triggers the efflux of neurotoxic substances
- To investigate the effect of the compound treatment on toxic burden and plasma biomarkers
- Market Access environment analysis
- Early communication with Regulatory and Market Access authorities

[1] *Prince M, Jackson J. International World Alzheimer Report 2009. Alzheimer's disease international (Adi); 2009 Sep.*

[2] *Wilmo A, Prince M. International World Alzheimer Report 2010: The Global Economic Impact of Dementia. Alzheimer's disease international (Adi); 2010 Sep.*

1.2 Relation to the work programme

- Indicate the work programme topic to which your proposal relates, and explain how your proposal addresses the specific challenge and scope of that topic, as set out in the work programme.

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EXPERT RECOMMENDATIONS for **Subsection 1.2 Relation to the work programme**

Analyse the whole description of the relevant part of the work programme: the specific challenge to be addressed, the scope of the topic, the expected impacts and explain as specifically as possible, item by item, how your project addresses the relevant topic, possibly using a table where you list requests by the topic and the related answers you propose (see example below). In this section 1.2 is where for the [illegible]time you have the **opportunity** to introduce and also [illegible]**rs' expectations on the impact** of your project.

EXAMPLE: **"AD-Project"**

The personalised health and care topic, **H2020-PHC-13** (a Research and Innovation action call), aims to create opportunities for real breakthrough research by supporting the translation of findings into the clinic. We are addressing Alzheimer's Disease (AD), a chronic non-communicable disease with increasing relevance. It is considered the "disease of the twenty-first century". Despite its public health importance and recent advances in understanding its molecular pathology, there exists no curative treatment or effective causative therapy. Approved treatments, including acetylcholine-esterase inhibitors (AChE-I) and N-methyl-D-aspartate (NMDA) receptor antagonists, have only modest symptomatic effects without targeting the underlying cause of the disease. No new treatments have been approved for AD since 2003. This emphasises the importance of further clinical research into novel causative strategies to combat the disease – such as the compound. The following **table** summarises the specific scope of this call, as set out in the SC1 work programme, and how it is addressed by the AD-Project project:

Specific scope of the topic	How AD-Project addresses the programme scope
Clinical trial(s) supporting proof of concept (PoC) in humans to assess the potential clinical efficacy of novel therapeutic concepts	» Proof-of-Concept (PoC) phase IIa2/b clinical trial to assess potential clinical efficacy of the compound in AD patients
Building on pre-existing pre-clinical research and additional results from large scale databases	» Preclinical in vivo and in vitro experiments demonstrated that the compound promotes export of brain derived toxic substances into the blood thereby reducing toxic levels and load in the CNS and improving learning deficits
Concise feasibility assessment justified by available published and preliminary results and supporting data as well as considerations of effectiveness and potential clinical benefits	» The compound has a well understood pharmacologic background and promising pharmacovigilance data. All information available today suggests that molecule will be a safe product. » Clinical benefit from the PoC RCT concerning the draining effect and the documented safety in AD patients

1.3 Concept and approach

- Describe and explain the overall concept underpinning the project. Describe the main ideas, models or assumptions involved. Identify any trans-disciplinary considerations;
- Describe the positioning of the project e.g. where it is situated in the spectrum from 'idea to application', or from 'lab to market'. Refer to Technology Readiness Levels where relevant. (See General Annex G of the work programme);
- Describe any national or international research and innovation activities which will be linked with the project, especially where the outputs from these will feed into the project;
- Describe and explain the overall approach and methodology, distinguishing, as appropriate, activities indicated in the relevant section of the work programme, e.g. for research, demonstration, piloting, first market replication, etc;
- Where relevant, describe how sex and/or gender analysis is taken into account in the project's content.

⚠ *Sex and gender refer to biological characteristics and social/cultural factors respectively. For guidance on methods of sex/gender analysis and the issues to be taken into account, please refer to http://ec.europa.eu/research/science-society/gendered-innovations/index_en.cfm*

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 1.3 Concept and approach**

Remember that evaluators are considering several proposals like yours, and it is fundamental for them to have available elements to figure out why **your** [illegible] most promising to receive funding. The section 1.3 is mainly asking to describe the five following elements: [illegible]**ain idea, 2. its positioning on the market, 3. any national/international R&I activities linked to your idea, 4. overall approach and methodology, 5. sex and gender analysis.**

Thus, to **highlight the innovation** in your approach, you should include:

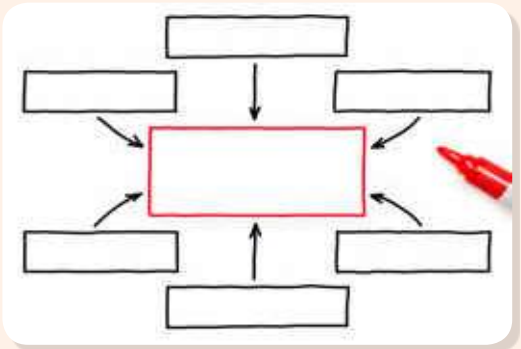
- a detailed but concise description of the solution;
- a description of the current stage of development or positioning of the project in the spectrum which goes from "**idea to application**".

For this last point you should explicitly refer to the **Technology Readiness Level (TRL)**, if that is meaningful. More information on TRL definitions can be found in **section G**. of the General Annexes, of Horizon 2020 Work Programme.

Position your project idea in the range from idea to application!

Where appropriate, mention **key milestones or potential proof for success** that led to the current stage (e.g. prototype, field trials, pilot studies with intended end-users and/or potential clients, past grants and awards for this project). If you have a patent(s), you should reference it/them and explain what it covers and where. This is evidence for the evaluator that your proposal is very likely to actually deliver what it promises.

In this section 1.3 you might insert a **flow chart** (see image shown) showing the phases of your project and the interconnection between them.



Insert also **names** of relevant initiatives or publications you base your work on in a note.

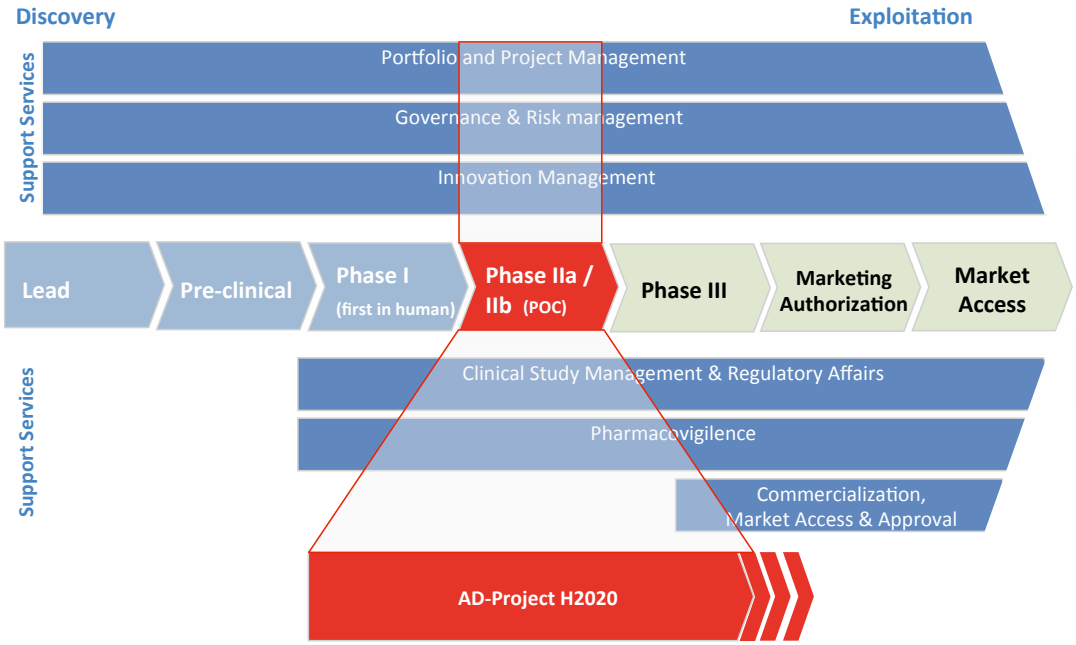
EXAMPLE: **"AD-Project"**

AD is hypothesised to be caused by an increased accumulation of toxic Aβ in the brain, followed by neurofibrillary tangles formation, synaptic and neuronal loss and brain atrophy, especially in the hippocampus and the frontal lobe. Although insoluble Aβ plaques were originally seen as the mediators of neurotoxicity, it has been reported that soluble oligomeric forms of Aβ are particularly neurotoxic. A recent study underpinning our herein proposed clinical trial demonstrates that impaired clearance and not increased generation of toxic Aβ peptides seems to be critical for the development of sporadic AD. These data suggest that molecular transport mechanisms which export soluble, toxic Aβ-aggregates may play a fundamental role in the pathogenesis of AD and could be a target for novel treatment.

Do not ignore sex and/or gender analysis

The herein proposed 24 month European multicenter study represents a **proof of Mechanism clinical trial** and includes the validation of cognitive effects of the compound (phase IIa) and a dose-finding study (phase IIb). Furthermore, safety and tolerability will be further validated and the compound dependent changes in Aβ plaque burden (via PET imaging) will be assessed. The **trial is designed as a randomised, double-blind, multicentre, placebo-controlled clinical trial** in early AD patients with MMSE (Mini-Mental State Examination) scores between 28-25.

Figure: Value Chain



Show with a graph how many female or male patients/customers you will involve, and their age range.

The AD-Project consortium is formed by renowned researchers from all over Europe, each one with a strong scientific and/or clinical background in the fields of AD cognitive research, biomarker research and / or AD imaging research. The trial will be conducted in 6 European clinical centres; those are DE 1 (recruiting 25 patients), DE 2 (recruiting 25 patients), NL (recruiting 30 patients), ES (recruiting 25 patients), IT 1 and IT 2 (each recruiting 25 patients). The consortium clinical centres involved are highly experienced in the diagnosis and management of AD clinical trials in accordance with Good Clinical Practice (GCP).

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 1.3 Concept and approach (Sex and gender analysis)**

A topic is considered **gender relevant** when it can be expected that its findings affect **women and men** or groups of women and men differently. In these cases, applicants should integrate gender issues and, when relevant specific studies, as part of the proposals. This is what is called by experts the **gender dimension** in research and innovation content. Addressing the gender dimension will contribute to the scientific quality and societal relevance of the produced knowledge, technology and innovation.

Moreover, applicants to Horizon 2020 are encouraged to promote equal opportunities in the implementation of the action and to ensure a **participation of women and men** at all levels in research and innovation teams and in management structures. Therefore, gender proportion among the personnel working in the proposal that will be primarily responsible for carrying out the research and/or innovation activities can also be highlighted (% of female or male researchers, administrative staff in the project etc). You might use a **graph** to show **gender presence and numbers of male or female patients involved**, and also mention the **age range** you will target. Explain the reason why a certain number of males and females will be included in the study's activities, etc. and if this proportion has been determined by some background statistics.

EXAMPLE: **"AD-Project"**

The inclusion of **women and men** in clinical trials improves the generalisability of research findings and is essential to ensure that women and men benefit equally from research. The herein proposed clinical trial AD-Project will include women and men at the age of 55 to 75 according to the demographic distribution of AD which in general affects more women than men.

Furthermore, within AD-Project, the **gender balance** is fairly equal with the assurance that individual researchers were chosen based on their expertise in the fields of Alzheimer's Disease, clinical trial development and management, legal and ethics expertise. When appointing scientific personnel within the context of the AD-Project project, the Consortium Partners will strive to ensure gender equality and that there is no gender discrimination.

1.4 Ambition

- Describe the advance your proposal would provide beyond the state-of-the-art, and the extent the proposed work is ambitious. Your answer could refer to the ground-breaking nature of the objectives, concepts involved, issues and problems to be addressed, and approaches and methods to be used.
- **Describe the innovation potential which the proposal represents.** Where relevant, refer to products and services already available on the market. Please refer to the results of any patent search carried out.

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 1.4 Ambition**

In this section you need to clarify for the evaluators your "**value proposition**", i.e., description of the offer described in terms of benefits for the users. To do this efficiently you need to define, in primis, who are the end users. That would make the rest of the section a lot more concrete.

The benefit to the end users must be described **compared** to the best available solution that exists on the market and **not only compared** to the absence of any solution. This will require discussion and brainstorming among all proposal partners as the value proposition should differentiate favourably your solution from competition or state of the art. Please also mention **complementary projects** (European, EU funded, or international) you plan to work with or mention the synergies with them that you plan to build.

KEY QUESTIONS to clarify your ambition:

- What are the market needs in your field?
- Do you know them first-hand (from an end user or future customer for your technology)?
- Are they currently partially met, or totally unmet?
- What is your ambition, in terms of meeting the market needs?
- What is your offer to the end user; how would an end user benefit from your technology?
- How much is your technology better (faster, cheaper, more reliable, more efficient, with less unwanted effects etc.) than the existing one?

Compare not only on a technological basis, but also mostly on how the problem is addressed today. Please be as specific as possible/necessary, even if you need to extrapolate existing research results in terms of estimating future parameters.

To clarify and summarise your ambition you might use such a table:

State of the art	[illegible]	How do you achieve the progress
1...		
2...		
3...		

In this section you might add a brief **SWOT analysis or just use this technique to define/refine your ambition** to the purpose of identifying and specifying **Strengths, Weaknesses, Opportunities, and Threats** (SWOT) for the proposed project. All those can be interconnected.

Organise a **brain storming** among all main project partners hearing the views of academics, clinical partners, SMEs, large enterprises, end-users etc.

Think big!

EU funds aim to improve the life of all citizens and your project should show how it will have a role in this change!

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A **SWOT technique** could help you to clarify the following elements:

- **Strenghts** (e.g., patents available; established network with relevant companies; successful tests already carried out...)
- **Weaknesses** (e.g., no real demonstration of the effectiveness of the method; shortage of resources – both human and financials...)
- [illegible] (e.g., things that work/may work in your favour: upcoming stricter regulations favouring your product; growing dissatisfaction with the quality of existing products...)
- **Threats** (e.g., things that work/may work against you: very diverse audiences, with diverse needs; access to public insurance may be necessary, thus it takes time which can create delays in the achievement of your results...)

Remember that in this section you can also show that the consortium is aware of [illegible]**information** available (existing patents, duration, value etc). Using patent information before funding/conducting research can increase the value of research and the opportunities for utilisation. This is a critical source of information that should be used by researchers and research funding agencies.

Show Intellectual Properties available in the consortium to increase your potential value

Finally, where possible, include a **first benchmarking** specifying improvement in performance, ease of use, cost-benefit, etc. compared to alternative solutions already into the market. This information can be presented independently, or be a part of your SWOT analysis.

How your project will differentiate and/or complement other projects or clusters of projects ?

EXAMPLE: **"AD-Project"**

The **ambition** of the AD-Project project is to confirm the compound as the first therapeutic disease-modifying agent of AD that targets the underlying cause of the disease. This European RCT is initiated and led by an SME which has assembled a consortium of several renowned European clinical AD researchers and different highly experienced, specialised European SMEs. The assembled consortium thereby combines complementary expertise in the fields of AD biomarker, imaging and cognitive testing with health economics, dissemination and exploitation.

The AD-Project has a strong innovation potential because we aim to shed further light on the use of biomarkers for early diagnosis and for monitoring disease progression including PET imaging and blood-based biomarkers. These biomarker-based procedures should be further established as conclusive predictive tools in clinical trials to distinguish responders from non-responders or to monitor effectiveness as well as future clinical trial drugs for AD.

2. Impact

ANNOTATION

EXPERT RECOMMENDATIONS for **Section 2. Impact**

The evaluators will pay particular attention to the **'Impact' criterion** and they will evaluate it to the extent to which project outputs will contribute to:

- the expected impacts described in the H2020 call;
- enhancing capacity and integration of new knowledge;
- strengthening the competitiveness and growth of the industrial partners by **developing** and **delivering innovations** meeting market needs;
- other **environmental or social impacts.**

The sections 2.1, 2.2 (a - b) in this chapter will give you the chance to explain your project expected impact, your dissemination, communication and exploitation strategies.

Impact touches several environments, not only Science

2.1 Expected impacts

⚠ *Please be specific, and provide only information that applies to the proposal and its objectives. Wherever possible, use quantified indicators and targets.*

Describe how your project will contribute to:

- the expected impacts set out in the work programme, under the relevant topic;
- improving innovation capacity and the integration of new knowledge (strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets; and, where relevant, by delivering such innovations to the markets;
- any other environmental and socially important impacts (if not already covered above).
- Describe any barriers/obstacles, and any framework conditions (such as regulation and standards), that may determine whether and to what extent the expected impacts will be achieved. (This should not include any risk factors concerning implementation, as covered in section 3.2.)

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 2.1 Expected impact**

Be specific on impact description!

As referenced above, the potential impacts of the project should be clearly detailed and highlight the improvement for European competitiveness. Make reference to what is outlined in the work programme as "expected impacts". For example, in the context of **improvements to the quality of life, active ageing, and improvements in the efficiency of health and care systems** you can refer to potential **savings for healthcare** systems by reduces hospitalisation costs. You can and should highlight the benefits of your method or offering by referring to **cost-effectiveness, health economics and marketing strategies.**

How would your solution change the existent market?

ANNOTATION

Be sure to identify indicators to measure the project impact; your work should lead to quantitative results. For illustrative purposes, we present some suggested impacts you could explore and develop in your project:

- **Improved therapy/diagnosis/care self-management and patient sense of security**
- **Patient empowerment or improved family quality of life**
- **Assistance to the weaker classes of the population**
- **Reduction in care management costs**
- **Improved patient-health professional interaction**
- **System replication**

Going deeper in the impact you want to create there is a need to assess several aspects. We suggest you go through these **KEY QUESTIONS**:

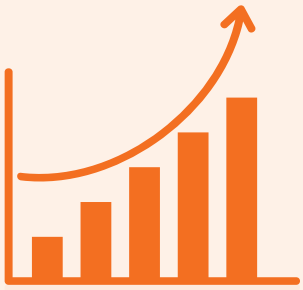
- **What would be the changes brought by introducing your innovation on the market?**
- **What is the expected growth potential of your solution in terms of turnover, employment, market size, IP management, sales, return on investment and profit, etc.?**
- **What are the estimated funding requirements to reach the market?**

You could create a scale of impact, starting from:

- **the scientific impact** on the researchers working in your field (e.g., define the scientific journals that you plan to publish this work on, as well as a timeline for this);
- the SMEs working in the related **technological field**, mentioning what is the **socio-economic impact** for the healthcare systems or in general on the final users/patients (e.g., how many patients/doctors/hospitals your project may be able to help);
- and finally consider any evolution on the **regulatory framework** that your project market might benefit from or even put in a risky situation (e.g., upcoming regulation making mandatory use of products similar to the output of your project).

Discuss also how your project can lead to **improved clinical decisions and health outcomes** and if the technology/service/product is extendable to other diseases (e.g., improvement in the percentage of early diagnosis of a disease).

Key Performance Indicators



Define your indicators

Discuss your impact on the **related stakeholders**. For example, why are they involved? How they will benefit from your innovation? And how they can support you?

E.g., if local authorities are interested in assisting ageing people communities, consequently, your innovation might be of interest for these authorities and they might be keen on supporting you.

standardisation

Remember that **contributions to technical standards** are also an impact. Explain how your project will contribute to technical standards, and which steps are already taken in this direction. For example, you could have a **standardisation body** as part of your consortium or have partners involved in leading roles in national standardisation committees. (e.g., for each group different subjects have already been identified and other will be identified during project activities). Inserting a table which contains the main sector, target groups, impact and indicators will help you to clarify your work (see table below).

Last but not least:
Discuss how do you plan the **continuity** of the project once funding is over.

ANNOTATION

Sector	Target Group	Impact
Authorities	Hospitals, regions, health managers	Improved service, increased confidence in decision support systems for disease/patient management and control of expenditure
Healthcare	Caregivers, medical doctors, patients, families	Improved self-management and management of diseases and/or expenditure
Market	SMEs	New market, new customers

EXAMPLE: **"AD-Project"**

As mentioned earlier, despite the global epidemic of AD, none of the AD treatments available today slows or stops the malfunction and death of neurons in the brain that cause AD and eventually make it fatal. In 2010, the Alzheimer's Association projected that the potential impact of a treatment breakthrough in 2015 that could slow the progression of AD would result in:

- The number of AD patients in the severe stage which require significant care would drop dramatically from 42% to 18% by 2020;
- More AD patients will be living in the mild stage of the disease (56%) than they would without a treatment breakthrough (28%);
- Once AD patients transitioned to the moderate stage, they would remain in that stage about five times longer than they do now;
- All of the above would substantially reduce the costs of care by 30% and the total costs to all payers by 17%;

The expected results from the AD-Project project is to provide Proof of Concept for the compound as disease-modifying and to pave the way for phase III RCT´s that along with planned Market Access activities would result in its fast future implementation as treatment of AD. As described above, such a therapeutic advance would have a significant impact on the global and European health and social care burden of this neurodegenerative disorder. Thus, the study has the potential impact to not only improve the health of future generations of European citizens, but also reduce the burgeoning healthcare costs on dementia care.

2.2 Measures to maximise impact

a) Dissemination and exploitation of results

Provide a draft 'plan for the dissemination and exploitation of the project's results' (unless the work programme topic explicitly states that such a plan is not required). For Innovation actions describe a credible path to deliver the innovations to the market. The plan, which should be proportionate to the scale of the project, should contain measures to be implemented both during and after the project.

⚠ *Dissemination and exploitation measures should address the full range of potential users and uses including research, commercial, investment, social, environmental, policy making, setting standards, skills and educational training.*

⚠ *The approach to innovation should be as comprehensive as possible, and must be tailored to the specific technical, market and organisational issues to be addressed.*

- Explain how the proposed measures will help to achieve the expected impact of the project. Include a business plan where relevant.
- Where relevant, include information on how the participants will manage the research data generated and/or collected during the project, in particular addressing the following issues:[2]

  - What types of data will the project generate/collect?
  - What standards will be used?
  - How will this data be exploited and/or shared/made accessible for verification and re-use? If data cannot be made available, explain why.
  - How will this data be curated and preserved?

  ⚠ *You will need an appropriate consortium agreement to manage (amongst other things) the ownership and access to key knowledge (IPR, data etc.). Where relevant, these will allow you, collectively and individually, to pursue market opportunities arising from the project's results.*

  ⚠ *The appropriate structure of the consortium to support exploitation is addressed in section 3.3.*

- Outline the strategy for knowledge management and protection. Include measures to provide open access (free on-line access, such as the 'green' or 'gold' model) to peer-reviewed scientific publications which might result from the project[3].

  ⚠ *Open access publishing (also called 'gold' open access) means that an article is immediately provided in open access mode by the scientific publisher. The associated costs are usually shifted away from readers, and instead (for example) to the university or research institute to which the researcher is affiliated, or to the funding agency supporting the research.*

⚠ *Self-archiving (also called 'green' open access) means that the published article or the final peer-reviewed manuscript is archived by the researcher - or a representative - in an online repository before, after or alongside its publication. Access to this article is often - but not necessarily - delayed ('embargo period'), as some scientific publishers may wish to recoup their investment by selling subscriptions and charging pay-per-download/view fees during an exclusivity period.*

[2] *For further guidance on research data management, please refer to the H2020 Online Manual on the Participant Portal.*

[3] *Open access must be granted to all scientific publications resulting from Horizon 2020 actions. Further guidance on open access is available in the H2020 Online Manual on the Participant Portal.*

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 2.2 a) Dissemination and Exploitation**

The terms "exploitation" and "dissemination" are defined under the Horizon 2020 Rules for Participation as follows:

- **Exploitation** "means the use of results in further research activities other than those covered by the action concerned, or in developing, creating and marketing a product or process, or in creating and providing a service, or in standardisation activities";
- **Dissemination** "means the public disclosure of the results by any appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium".

We will focus our recommendations on exploitation issues.

The exploitation of the project results should be an activity that starts at the beginning of the project and it is important that it is **proportionate** to the project scale; it is an issue that requires a clear strategy from the beginning and is given frequent attention during the lifetime of the project. It is considered good practice to propose **the exploitation plan, "Plan for the Exploitation and Dissemination and Exploitation of Results"** at the beginning of the project and update it throughout the project implementation, including the plan for the consortium as a whole, and for each individual partner.

Ownership distribution of project results is strictly related to exploitation and is key for its sustainability and its potential commercial exploitation. The starting point for the definition of results ownership will be the drafting of a **list containing expected exploitable** results and the related identification of **background** information that allowed the successful development of each single project phase (especially in Innovation Actions).

This section should contain a **clear plan for post-project translation to market, market entry and commercial viability**, together with strategies for tackling market entry barriers. The exploitation strategy must be sound!

Remember: the more specific you are about this commercialisation path, the higher is your credibility.

If possible, explain **your numbers and estimations** bottom-up (e.g., "the market for our product is 100 people. Of those, we can access 70. As our solution is superior to competition, we expect to get at least 35 of these people as customers. 35*price=revenues) and not top-down ("we want to conquer 1.78% of the world market of XYZ capturing revenues of … million").

If you offer the evaluators a **first glance on the market analysis**, you might use the "**5 Cs**"; **Company, Customers, Competitors** (these must be defined in terms of consumers' needs, not in terms of technology), **Collaborators, Context.**

1. Company
2. Customer
3. Competitors
4. Collaborators
5. Context

ANNOTATION

KEY QUESTIONS to emphasise your exploitation strategy:

- **How you will deliver your innovation to the market?**
- **Is the partner bringing your innovation to the market already part of the consortium?**
- **If not, do you already know possible candidates?**
- **How will the interested partner get access to the technology (own Intellectual Property, licensing, acquiring IP)?**
- **When will the partner get access to the technology and how will other partners contribute later on?**
- **Who are your customers?**
- **What is your sales strategy, i.e. how do you deliver the offer to customers?**
- **Development strategy, i.e. what are the main steps of expansion?**
- **Communication strategy, i.e. how do you promote and create the awareness of the market as regards the offer?**
- **Do you want to create a new unit to bring your innovation to the market (start-up, spin-off company)? Why would you want to do so? Is there a team already in place to do this?**

Evaluate the **go to market strategy** carefully – explain which factors will be taken into account in the decision making process. Make sure, that all the necessary IP needed for a marketable solution is available at non-prohibiting cost. This includes background Intellectual Property (IP) already existing as well as results you plan on creating.

Supplement your expected project results and exploitation with figures and tables! Please, note that "traditional" kind of expenses like **patent filings, licences and royalties** continue to be eligible in Horizon 2020.

Health-2-Market has included in this template a business plan executive summary and a WP example on Dissemination and Exploitation

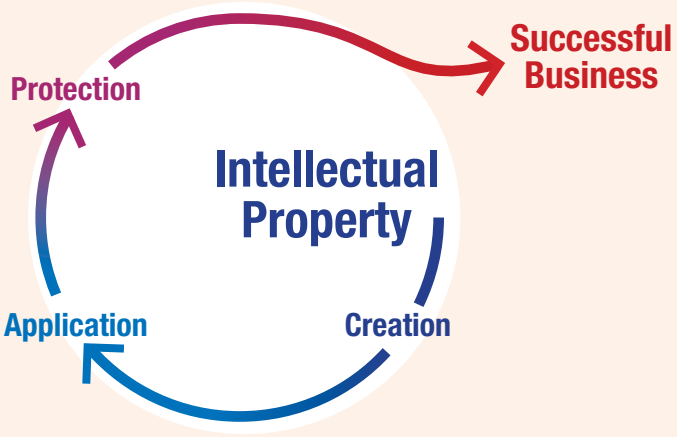
A detailed business plan is especially relevant for Innovation Actions, i.e. projects with high Technology Readiness Level (TRL). However, a **business plan for Research and Innovation Actions**, in less detailed form, will help your proposal by demonstrating that you have a clear idea about the **exploitation routes, risks, need for private and public funding.**

If the research is in its initial stages, the risks will be bigger and a business plan should account for them (e.g., that the research does not produce the expected results, that the results produced are too expensive to be marketed right now, etc.).

If you do not already have a business plan, this represents an opportunity to create one to better understand exploitation issues such as market demand, intellectual property identification and protection, business models, customer segments, marketing, and other topics. For more information on creating a business plan, you may reference any number of resources online including some that can be found through the H2M website and the Guidebook "Innovation Strategy in R&D projects". http://www.health2market.eu/results/step-by-step-guide

In addition to the example below, we have included in the Appendix 2 an **example of a business plan executive summary**, and in the Appendix 3 examples of **work packages** that address **dissemination** and **exploitation** of results, as well as **preparation of market authorisation and market access**.

ANNOTATION



For a **commercialisation of your technology** with an optimal financial return for you, your organisation, or the commercialising partner organisation, protection of IP (intellectual property = knowledge, technologies, procedures, processes,…) is essential. If you have a patent, mention it and explain what it covers and where. Outline both the IP you expect to be generated during the project and the ways you want to protect it. Consider that there are other options as the ubiquitous patent like utility patents, trade secrets or specific protection options plant breeders' rights and integrated circuit layout design protection.

Think of a coherent **strategy to protect your IP** or explain, why IP protection is not necessary or not part of your exploitation model (e.g., open source models). Involve the partners most closely that are closest to the market and to the end user application you have in mind. Your IP protection strategy should be clearly linked to your exploitation strategy. These aspects shall be further detailed into the Consortium Agreement and they may be needed to be updated throughout the project duration.

Explain the **regulatory and/or standard requirements** to be fulfilled for the exploitation of the technology/product/solution or concept: how they are to be met.

Regarding **scientific publications**, remember that open access is mandatory in Horizon 2020 projects, and it can be costly, depending on the journal (1000-1500 EUR per publication is not an exception). Indicate measures to provide open access, and plan relevant costs, if any!

EXAMPLE: **"AD-Project"**

For this project to fully realise its benefit for people in Europe with AD and other key stakeholders, the AD-Project project will ensure that the potential benefit of this novel disease-modifying compound is maximised. This will be accomplished through early involvement of Competent Authorities (Regulators) as outlined in the objectives and WP7 dedicated to "**Preparation of Market Authorisation and Market Access**".

We aim to establish early communication with **Regulators and Market Access institutions** on the national and European level to obtain joint and/or parallel scientific advice respectively on putative comparators and further outcome parameters for both Market Authorisation and Market Access. This strategy will include immediate **negociations with the EMA and/or National Competent Authority** and Market Access institutions to establish the AD-Project as a pivotal clinical trial. Some initial discussions are already happening. In addition we will evaluate the Market Access environment followed by the development of a preliminary plan to support and prepare for the commercialisation of the compound in the European market. This will ensure that future **commercialisation will bring this therapy to AD patients without delay and reimbursed.**

b) Communication activities

Describe the proposed communication measures for promoting the project and its findings during the period of the grant. Measures should be proportionate to the scale of the project, with clear objectives. They should be tailored to the needs of various audiences, including groups beyond the project's own community. Where relevant, include measures for public/societal engagement on issues related to the project.

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 2.2 b) Communication Activities**

Under Horizon 2020, you have a general obligation to "promote the action and its results." The communication activities to be undertaken during the action's lifetime must already be part of the proposal (either as a specific work package for communication or by including them as a task in another work package, depending on the size of the project and the resources you need to invest on this). They are taken into consideration as part of the evaluation of the criterion 'Impact'.

The communication activities must be planned and implemented from the outset (and continue throughout the entire action), with a comprehensive communication plan that defines clear objectives (adapted to various relevant target audiences) and sets out a concrete planning for the communication activities including a description and timing for each activity.

A good strategy should:

- start at the outset of the action and continue throughout its entire lifetime;
- be strategically planned and not just be ad-hoc efforts;
- use the right medium and means;
- identify and set clear and measurable communication objectives (e.g., have final and intermediate communication aims been specified? What impact is intended? What reaction or change is expected from the target audience?);
- be targeted and adapted to audiences that go beyond the project's own community including the media and the public (e.g., is each target audience a relatively homogenous group of people? Can the target audience help the action achieve its objectives?).

An overview of best practices and a checklist on how actions can build a communication strategy is available in the H2020 Online Manual.

EXAMPLE: **"AD-Project"**

Dissemination is considered a key factor to the success of the AD-Project project. The project has a work package dedicated to "Dissemination, communication and exploitation". The work package leader is Company XYZ. Company XYZ is a European-wide well-known manager of cross-organisational projects as well as process moderator for the initialisation and implementation of pilot actions between public research organisations and business companies. This partner already works closely together with the consortium to implement a common strategy. It will consist of ongoing activities involving all partners aimed at increasing project awareness both in the scientific community and other target user groups (e.g. patient organisations, industry) that can benefit from the results of the project. The most appropriate channels to disseminate project results have been chosen by the consortium to present the research work and to inform stakeholders during and after the project end.

See **Appendix 3 for example of the work package "Dissemination and exploitation".**

3. Implementation

3.1 Work plan — Work packages, deliverables and milestones

Please provide the following:

- brief presentation of the overall structure of the work plan;
- timing of the different work packages and their components (Gantt chart or similar);
- detailed work description, i.e.:
  - a description of each work package (table 3.1a);
  - a list of work packages (table 3.1b);
  - a list of major deliverables (table 3.1c);
- graphical presentation of the components showing how they inter-relate (Pert chart or similar).

⚠ *Give full details. Base your account on the logical structure of the project and the stages in which it is to be carried out. Include details of the resources to be allocated to each work package. The number of work packages should be proportionate to the scale and complexity of the project.*

⚠ *You should give enough detail in each work package to justify the proposed resources to be allocated and also quantified information so that progress can be monitored, including by the Commission.*

⚠ *You are advised to include a distinct work package on 'management' (see section 3.2) and to give due visibility in the work plan to 'dissemination and exploitation' and 'communication activities', either with distinct tasks or distinct work packages.*

⚠ *You will be required to include an updated (or confirmed) 'plan for the dissemination and exploitation of results' in both the periodic and final reports. (This does not apply to topics where a draft plan was not required.) This should include a record of activities related to dissemination and exploitation that have been undertaken and those still planned. A report of completed and planned communication activities will also be required.*

⚠ *If your project is taking part in the Pilot on Open Research Data[4], you must include a 'data management plan' as a distinct deliverable within the first 6 months of the project. A template for such a plan is given in the guidelines on data management in the H2020 Online Manual. This deliverable will evolve during the lifetime of the project in order to present the status of the project's reflections on data management.*

Definitions:

'Work package' means a major sub-division of the proposed project.

'Deliverable' means a distinct output of the project, meaningful in terms of the project's overall objectives and constituted by a report, a document, a technical diagram, a software etc.

'Milestones' means control points in the project that help to chart progress. Milestones may correspond to the completion of a key deliverable, allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems have arisen, corrective measures can be taken. A milestone may be a critical decision point in the project where, for example, the consortium must decide which of several technologies to adopt for further development.

[4] *Certain actions under Horizon 2020 participate in the 'Pilot on Open Research Data in Horizon 2020'. All other actions can participate on a voluntary basis to this pilot. Further guidance is available in the H2020 Online Manual on the Participant Portal.*

3.2 Management structure and procedures

- Describe the organisational structure and the decision-making (including a list of milestones (table 3.2a))
- Explain why the organisational structure and decision-making mechanisms are appropriate to the complexity and scale of the project.
- Describe, where relevant, how effective innovation management will be addressed in the management structure and work plan.

⚠ *Innovation management is a process which requires an understanding of both market and technical problems, with a goal of successfully implementing appropriate creative ideas. A new or improved product, service or process is its typical output. It also allows a consortium to respond to an external or internal opportunity.*

- Describe any critical risks, relating to project implementation, that the stated project's objectives may not be achieved. Detail any risk mitigation measures. Please provide a table with critical risks identified and mitigating actions (table 3.2b)

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 3.2 Management structure and procedures**

Innovation Management (IM) should be ideally interconnected with the management structure of the project; in principle, a **definition** for an Innovation Management system is the following:

IM systems can be described as structured and regularly practiced ways of running organisational activities contributing to its innovativeness capacity and performance, including organisational structure, responsibilities, procedures, practices, activities and resources needed for the development, implementation, achievement and maintenance of organisational policies and objectives.[5]

The skills required to **manage innovation effectively** differ from general management principles as it demands that managers match technical expertise with soft skills. To promote creativity, areas such as technology and project management are in need of integration with people management, plus managers need to be alert about risk management![6]

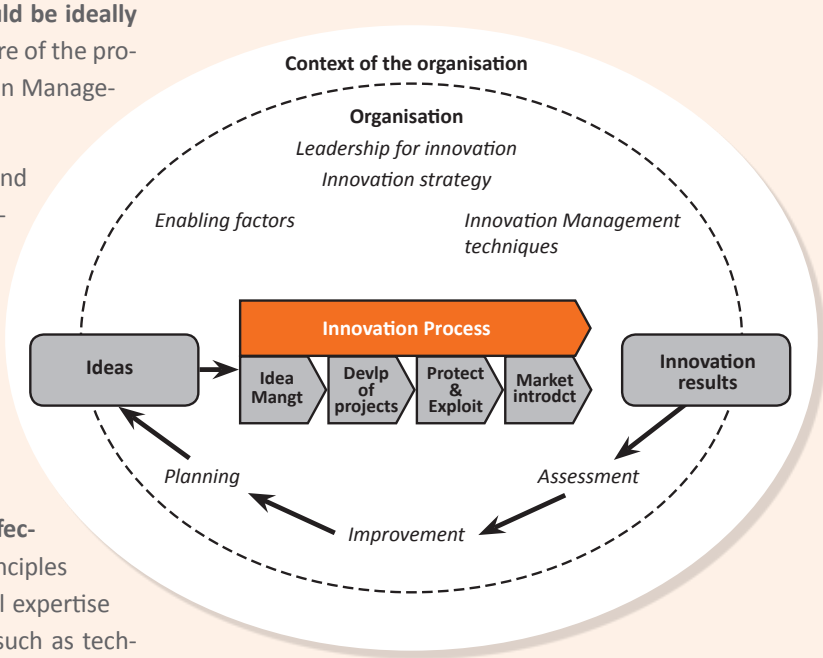


Figure based on CEN/TS 16555-1 figures 1+2

ANNOTATION

In a collaborative project of Horizon 2020 it is advisable to appoint an **innovation manager to be part of the management structure**, undertaking the main exploitation activities of the project. This manager is also aimed to support the (industrial) partners in setting up their individual business plans, while in cooperation with the Project Committee will handle IPR related issues.

Name this specialist, along with some of his/her/its greater accomplishments in the area. Simply mentioning "our university also has a tech transfer department which will take care of…" doesn't reinforce the project innovation potential. Instead, it is advisable to take care of it and specify how partners will work on **commercial exploitation** during the project and how you manage the process. Include a **budget** being able to support this and make it at least a **task**, or even better a **work package on innovation management**. Mention procedures on how to manage IP and how to deal with conflicts. Include **deliverables and milestones** with regard to innovation process and enforce them.

- Ideally, the partner in charge of innovation management also has a commercial interest in the technology getting successfully commercialised. It's important that the **innovation manager** works hand-in-hand with the **project coordinator.**
- Summarise the main hurdles and main risks to be mastered during the project implementation. Consider, for example, **technological risk, human risk, financial risk,** acceptation by the market, regulations, timing to market... Indicate risks, their probability, the responses in case the risk should occur and the contingency plan. Remember that the evaluators are probably experts in the area, so they know the risks even if you don't mention them. So your best strategy is to show that you know the risks, and are prepared to face them.
- In some cases, it might be of added value for the management structure of your project, especially in Innovation Actions, to create an **IPR-Exploitation Board** to deal with IPR and exploitation issues and to report to the Executive Board (composed by work package leaders), General Assembly (where all beneficiaries are represented) or other project management bodies. If you plan such IPR-E Board, explain briefly its functions and composition.

[5] Tang 2003 - [6] Goffin e Mitchell 2005

3.3 Consortium as a whole

⚠ *The individual members of the consortium are described in a separate section 4. There is no need to repeat that information here.*

- Describe the consortium. How will it match the project's objectives? How do the members complement one another (and cover the value chain, where appropriate)? In what way does each of them contribute to the project? How will they be able to work effectively together?
- If applicable, describe the industrial/commercial involvement in the project to ensure exploitation of the results and explain why this is consistent with and will help to achieve the specific measures which are proposed for exploitation of the results of the project (see section 2.3).
- **Other countries:** If one or more of the participants requesting EU funding is based in a country that is not automatically eligible for such funding (entities from Member States of the EU, from Associated Countries and from one of the countries in the exhaustive list included in General Annex A of the work programme are automatically eligible for EU funding), explain why the participation of the entity in question is essential to carrying out the project

ANNOTATION

EXPERT RECOMMENDATIONS for **Subsection 3.3 Consortium as a whole**

In this section the composition of the consortium will be included.

It is suggested to explain and emphasise in this section 3.3 the involvement of each partner in the exploitation and dissemination activities.

EY QUESTIONS to emphasise who in your consortium will take care of innovation/exploitation/IPR:

- **What they will do in terms of innovation/ exploitation?**
- **Who will be the innovation manager?**
- **Who will deal with Intellectual Property?**
- **Who will deal with market analysis?**
- **Who will deal with consumer needs?**
- **Who will deal with communicating to health care organisations, patients, clients, companies? etc.**

You could include a graph which shows the consortium expertises divided by activities.

3.4 Resources to be committed

⚠ *Please make sure the information in this section matches the costs as stated in the budget table in section 3 of the administrative proposal forms, and the number of person/months, shown in the detailed work package descriptions.*

Please provide the following:

- a table showing number of person/months required (table 3.4a);
- a table showing 'other direct costs' (table 3.4b) for participants where those costs exceed 15% of the personnel costs (according to the budget table in section 3 of the administrative proposal forms).

ANNOTATION

EXPERT RECOMMENDATIONS for **Sub-Section 3.4 Resources to be committed**

Remember to **plan and allocate resources** not only for "**personnel costs"** specifically for exploitation and dissemination activities, but also allocate "other direct costs" related to the exploitation and dissemination activities. These costs can be necessary in case:

- **you need to purchase data for market analysis**
- **plan to file patents**
- **you need to publish**
- **you need to participate to International Congresses or technology market places / brokerage events or investors forums**

This might require significant costs so please carefully evaluate what you will need in advance!

Hoping you will take advantage of the suggestions we elaborated, we thank you for having read the ARIaT and we encourage you to consult the different official sources of information which European Commission has granted. These sources – as well as other useful materials - are listed below.

Relevant useful materials

Horizon 2020 Participant portal

http://ec.europa.eu/research/participants/portal/desktop/en/home.html

Research and Innovation Actions template

(Horizon 2020)

http://ec.europa.eu/research/participants/data/ref/h2020/call_ptef/pt/h2020-call-pt-ria-ia_en.pdf

Health-2-Market project materials and results:

http://health2market.eu/results/

A step by step guide "Innovation Strategy in R&D projects":

the guide explains why and when the innovation strategy is required in R&D projects, and how it should be developed and implemented. The guide consists of several independent chapters: (1) Key aspects of innovation strategy; (2) Innovation strategy preparation; (3) Innovation strategy implementation step by step (commercialisation routes and business models, Intellectual Assets and Intellectual Property, Business Plan, Marketing Strategy, Financing, EU legislation, standardisation and certification issues); (4) Innovation strategy follow up and evaluation. Concrete, real life examples are provided to illustrate each topic, along with FAQs, important points to remember and other learning tools. The guide is relevant to R&D practitioners working either on collaborative R&D projects, or in company internal projects, and aiming to bring research results to market.

http://www.health2market.eu/results/step-by-step-guide

MOOC on "Roadmap to Entrepreneurial Mindset and Toolkit", available on Udemy

A MOOC (massive open online course) developed by SKEMA Business School in Health-2-Market project. Although the course has been developed with a health sciences focus, it is open to any researcher, coach and professional interested in grasping a better understanding of business opportunity development in the life sciences environment. The course provides an integrated and systemic toolkit, that SKEMA Business School has tested on many projects over the past 15 years in postgraduate and executive programs, which includes: (1) Building the scope of the project with ISMA 360; (2) Designing the business model; (3) The business plan; (4) Working out your financial objectives; (5) Checking your business plan for the pitch.

https://www.udemy.com/entrepreneurial-mindset-and-toolkit/

Health Competence

This website includes all projects related to life science and health supported by the European Commission since 2004. It gives visibility to organisations and scientists involved in these projects and, together with interactive search devices, facilitates the identification of potential collaboration partners and the set up of partnerships between academia and industry in health research. Health Competence will also progressively give access to the research results in terms of technology offers, patents and publications.

http://www.healthcompetence.eu/converis/publicweb/area/1353

Fit For Health 2.0

Fit for Health 2.0 aims to promote and enhance a sustainable participation of European industry in the health-related sector of Horizon 2020 (H2020). This EC-funded project offers a set of cost-free courses, activities, methods and tools corresponding to the innovation cycle of an EU project, and provides a lot of relevant resources.

http://www.fitforhealth.eu/

Fit for Health trainings on exploitation and knowledge transfer

http://www.fitforhealth.eu/training-calendar/upcoming/?target=Project+TTs

Health NCP NET 2.0

http://www.healthncp.net/health-ncp-net-hnn-20

Health NCPs are individuals nominated by their governments with the mandate to spread awareness, provide specialist advice and on-the ground guidance on Health research funding opportunities within Horizon 2020 and ensuring that the programme is readily accessible to all potential applicants. Health NCPs can guide anyone interested in applying for European funding in health research to identify the right call, guide and support you through the different stages of an application.

European IPR Helpdesk

The European IPR Helpdesk offers free of charge, first-line support on IP and IPR matters to beneficiaries of EU funded research projects and EU SMEs involved in transnational partnership agreements
http://www.iprhelpdesk.eu/library

Fact sheet on "The Plan for the Exploitation and Dissemination of Results in Horizon 2020"

https://www.iprhelpdesk.eu/sites/default/files/newsdocuments/FS-Plan-for-the-exploitation-and-dissemination-of-results_1.pdf

Fact sheet on "IP Management in Horizon 2020: project proposal"

http://www.iprhelpdesk.eu/FS_IP_Management_H2020_proposal

Fact sheet on "IP management in Horizon 2020: grant preparation"

http://www.iprhelpdesk.eu/FS_IP_Management_H2020_preparation

Fact sheet on "IP management in Horizon 2020: project implementation and conclusion":

http://www.iprhelpdesk.eu/FS_IP_Management_H2020_implementation

Appendices

APPENDIX 1 - Set of criteria for evaluators

Criterion 1 - Excellence

Current score: - / 5 ; Threshold 4; Weight 100% ; Priority 1

Note: The following aspects will be taken into account, to the extent that the proposed work corresponds to the description in the work programme. If a proposal is partly out of scope, this must be reflected in the scoring, and explained in the comments.

- Clarity and pertinence of the objectives
- Credibility of the proposed approach
- Soundness of the concept, including trans-disciplinary considerations, where relevant
- Extent that proposed work is ambitious, **has innovation potential**, and is beyond the state of the art (e.g. ground-breaking objectives, novel concepts and approaches) *

Criterion 2 - Impact

Current score: - / 5 ; Threshold 4; Weight 100% ; Priority 2

Note: The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or international level:

- The expected impacts listed in the work programme under the relevant topic
- Enhancing **innovation capacity** and integration of new knowledge
- Strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets, and where relevant, by delivering such innovations to the markets
- Any other **environmental and socially important impacts** (not already covered above)
- Effectiveness of the proposed measures to **exploit and disseminate** the project results (including management of IPR), to communicate the project, and to manage research data where relevant*

Criterion 3 - Quality and efficiency of the implementation

Current score: - / 5 ; Threshold 3; Weight 100% ; Priority 3

Note: The following aspects will be taken into account:

- Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks and resources
- Complementarity of the participants within the consortium (when relevant)
- Appropriateness of the management structures and procedures, including **risk and innovation management** *

APPENDIX 2 - Example of a business plan executive summary

Business Plan – the AD-Project Company
Executive Summary

Business Description: Although the AD-Project Company has already embarked in several projects to develop diagnostics for autoimmune and neurodegenerative diseases like Alzheimer's Disease (AD), the Company's current focus is mainly based on development of *the compound* as a therapeutic for AD.

Product Description: The compound has been thoroughly tested in vitro and in animal trials for Alzheimer's Disease. The results have been very well published in peer reviewed journals and discussed by leading experts and opinion leaders in key forums.

The discovery and development of new medicines is essential to address the unmet needs of our most challenging and devastating diseases. This is particularly true for Alzheimer's Disease, where the development of innovative new medicines to prevent or slow the disease's onset and progression will have a profound impact on the lives of millions of people who face it today and in the future.

Market Opportunity: Alzheimer`s Disease is by far the most common dementia of later life and the leading cause of disability and death in the aged population. According to the World Health Organisation it affects 36 million people worldwide[(1)]. Due to demographic changes an estimated number of 115 million people worldwide will be suffering from AD by 2050. Accordingly, current and especially future health care systems are faced with tremendous costs. In 2010, the global economic impact of AD and other dementias was US$604 billion[(2)]. There is a tentative estimate of an 85% increase in costs to 2030. Despite its public health importance and recent advances in understanding its molecular pathology, no disease-modifying drug exists up to date that can halt or at least slow down the progression of AD. Present treatment strategies only provide minimal short-term benefit due to limited symptomatic treatment without targeting the underlying mechanism of AD. Owing to its putative causative role in AD, amyloid β (Aβ) has become a primary target for disease-modifying therapeutics of AD. However efforts to develop causal therapies have so far been unsuccessful.

Competitive Analysis:
Currently, there are no AD medications on the market that can stop or significantly slow the disease from progressing. The presently available drugs for the treatment of AD (cholinesterase inhibitors (AChE-I) and memantine, a non-competitive N-methyl-D-aspartate receptor antagonist) only offer minimal symptomatic relief without addressing the underlying cause of AD. AChE-I and memantine can cause severe side effects and, if effective, alleviate disease symptoms up to 6–12 months only in patients with mild to moderate AD [(3, 4)]. However, most patients respond poorly or not at all to the therapy. There is no convincing evidence for an effect on disease progression of these drugs [(5, 6)]. Thus, there is clearly a great unmet need for new therapies that target the underlying cause of AD, reverse symptoms, or prevent AD completely.

Several putative disease-modifying drugs developed to reduce β-amyloid (Aβ) production, to prevent Aβ aggregation, to promote Aβ clearance, or targeting other pathological mechanisms are under development, but so far none has demonstrated efficacy in phase III trials [(6)]. Passive immunotherapy with monoclonal antibodies against Aβ are in late clinical development but phase III clinical trials with Bapineuzumab and Solanezumab failed to show an improvement or stabilisation of cognition or function. Other trials investigating different monoclonal antibodies are ongoing [(5-7)]. Up to now no drug for the disease-modifying treatment of AD has been approved. This represents an urgent unmet need resulting in clinical, social, and economic challenge.

Company Status and Milestones: The Company has succeeded in skipping phase I clinical trials based on the historical data of the present indication of the compound. With the described planned Proof-of-Concept clinical trial in mind, the next milestone will be to complete the actual RCT. Subsequent milestones include securing funding for planned phase IIa/b "clinical trial with public grants or in closing a milestone based agreement with Pharmaceutical Industries for the development of the next phases.

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APPENDIX 3 - Example of **work packages** addressing **dissemination and exploitation of results,** as well as **preparation of market authorisation and market access**

Work package number	6	Start Date or Starting Event				Month 1	
Work package title	Dissemination and exploitation						
Participant number							
Short name of participant							
Person/months per participant:							

Objectives

The main objectives of this work package are:

- to define and update the project dissemination plan including communication strategies and concrete activities to spread and promote the project outcomes within the scientific and medical communities as well as to a wider public and to create awareness on the subject (i.e. individuals, patient organisations, regulatory bodies);
- to conduct outreach to main industry stakeholders (i.e. Pharma, Medical Technology and Medical Imaging), in the EU Member States and Associated Countries in order to seek interested partners and/or additional private/public funding for possible Market Access/entry phase
- to develop an exploitation plan for the commercial valorisation of the project outcomes including strategies for Marketing authorisation and Market Access

Description of work

The work is divided into three tasks:

Set-up communication and dissemination activities

To widely disseminate the project concept, developments and results to the general public as well as the scientific and medical community, we are using effective communication means and strategies as follows:

- Creation of a project communication and dissemination plan, outlining the process of dissemination planned for AD-Project, including the development of supportive communication tools;
- Development of a project brand identity, e.g. project logo, to reinforce the project's external image, as well as setup and maintenance of a user friendly AD-Project project website. The website will be regularly updated with new content and research findings; protected and internal information will be maintained within the project's own workspaces for exclusive use of the RCT sites and project partners;
- Creation and maintenance of an email distribution list targeting AD relevant stakeholders, such as scientific communities, patient organisations, regulatory bodies, industry stakeholders, etc., to distribute e-newsletters;
- Preparation of open access scientific publications and articles in peer-reviewed academic journals as well as lay journals;

Task 6.2 **Awareness rising and outreach to stakeholders**

- The project partner will in liaison with the coordinator to advise and provide support to activities targeted at raising awareness and promoting the projects visibility, especially to relevant stakeholders. The following activities are planned:
- Presentation of the project and its outcome to relevant stakeholders, such as patient organisations, national and EU dementia/aging initiatives and networks (e.g. the AGE Platform Europe, the Joint Programming Initiative (JPI) "More Years, Better Lives", etc.) as well as industry stakeholders (e.g. pharmaceutical companies etc.);
- Presentations at national and international conferences in AD, dementia and neurodegenerative disease such as ICAD. This will help to promote the translation of the research output of this project into clinical practice and advance global health of AD patients;
- Initiation and organisation of forums or workshop with relevant stakeholders in order to discuss the project as well as general developments and prerequisites in the field of AD and dementia;
- Organisation of press conferences with journalists for widespread dissemination of the project, its activities and results;
- Organisation of a final dissemination conference with all partners to disseminate the project to the scientific community and the public.

Exploitation and sustainability

In order to ensure sustainable use of project results, AD-Project will develop an exploitation plan at the early project stages and continuously check upon exploitable assets. The sustainable use of the activity developed and in particular the RCT results will be followed up closely. From the beginning of the project, specific attention will be given to the protection and exploitation of Intellectual Property of results derived from project activities.

The following exploitation activities are planned:

- Protection of the outcomes and results of the AD-Project clinical trial according to the signed cooperation agreement as well as the development of a common exploitation strategy on how to deal with unexpected results;
- Search for subsequent public and/or private funding sources to conduct the subsequent clinical phase III trial with the help of targeted investor materials; this includes the search for
  - Public funding sources;
  - Industry partners in the pharmaceutical and diagnostic sector to fund the enlarged clinical study or license the IP generated by or incorporated in AD-Project;
  - Innovative public-private partnerships.

Deliverables

D6.1 Dissemination plan (M3)
D6.2 Project web site (M6)
D6.3 Exploitation and sustainability plan (initial M3, final M48)
D6.4 Targeted investor relations materials (M36)

Work package number	7	Start Date or Starting Event				Month 1	
Work package title	Preparation of Marketing Authorisation and Market Access						
Participant number							
Short name of participant							
Person/months per participant:							

Objectives

The main objectives of this work package are:

- to prepare for Marketing authorisation and to analyse and to evaluate the Market Access environment in the targeted European Markets as the basis for all product related Market Access considerations
- to develop a preliminary plan for Price Negotiations and Reimbursement of the compound in each targeted European Market

Description of work

The leader of this WP is a well-known Market Access consulting company which strategically advises research driven companies on various indications. They will provide strategic and operational support ranging from strategic advice regarding trial design (comparators, design, power) to stakeholder consultation meetings and full service regarding management and writing of Early Benefit Assessment Dossiers. Additionally, they will provide strategic input and support price negotiation meetings and preparation for the reimbursement decisions and has been a consultant in various European projects regarding health care policy and Market Access issues.

The AD-Project team will ensure insights and an optimal information flow to allow for timely input in subsequent project decisions. The work package leader will address the respective Market Access topics and provide an initial report which forms the basis for subsequent discussions within the steering and project teams. This will be paralleled by constant environment scanning regarding key factors to identify opportunities and to reduce risks and uncertainties throughout the project period as much as possible.

The work is divided in four tasks:

Task 7.1 **Prepare Marketing Authorisation through early communication with Regulators and Market Access institutions**

In the light of the envisaged Marketing Authorisation, it is key to early and intensively consult with the Regulators and the Market Access institutions with regard to the comparator (gold standard) to be used in Phase III Clinical Trial(s). This process will be initiated in our target European country to obtain relevant scientific advice and then will be extended to EU (e.g. EMA and EUnetHTA) to obtain additional scientific advice. To gain best possible understanding of the requirements of the national regulatory institutions and Market Access institutions especially with regard to the requested and accepted comparator(s) and ensuring that both Regulators and HTAs are in agreement is one of the main tasks of regulatory and medical specialists in this task.

Task 7.2 **Market Access Environment Evaluation**

Analysis of Market Access Environment

The main task in the Market Access environment evaluation is identifying, segmenting and targeting the influences on prescribers, patients and payers. However, the decision making landscape has become very complex with multiple types of stakeholders with intertwined relationships. We will identify the European key stakeholders and understand their needs as well as their relationships with each other.

In a first step the WP leader will initially analyse and evaluate the national health care systems of the EU Member States targeted to provide an overview of the Market Access Environments.

In a second step the WP leader will analyse relevant Market Access trends/upcoming changes in these systems, including changes in Market Access regulations.

In a third step the WP leader will monitor and evaluate relevant Market Access trends/ changes throughout the project phase.

Input for clinical development programmes:

WP leader will provide input regarding comparator products to be chosen in clinical development programmes from a Market Access and reimbursement point of view by using its own expertise and by performing appropriate desktop research. In its role as a strategic consultant to many research driven pharmaceutical companies, WP leader is well aware of the difficulties in aligning complex (multinational) clinical development programmes with national or regional specific requirements as well as market access challenges, including pricing and reimbursement issues.

The choice of comparator products has gained increasing importance for Market Access in the targeted countries over the years as well. In Germany, for example, due to the AMNOG-legislation (effective January 1st, 2011) the choice of the adequate comparator in clinical development programmes is a key element to consider, when preparing for optimal Market Access of new drugs.

The development programme as it is currently planned will allow to adequately and timely consider the respective comparator treatments (gold standard, relevant comparative therapy when designing the study programmes. This is a significant advantage to many "traditional" clinical development programmes, thus avoiding difficulties in the benefit assessment after the launch.

Task 7.3 **Develop preliminary plan for ensuring later Market Access**

In a first step, based on the data collected and evaluated so far, a strategy will be developed to ensure that the requirements arriving from the regulators side and the requirements of the national Market Access institutions are known and understood.

Information collected from the Market Access viewpoint will include:

- Knowledge of healthcare systems in different countries and the respective regulative requirements
- Identification and understanding of relevant stakeholders in the markets
- Reimbursement status of current treatments and restrictions
- Understanding of disease management
- Relevant clinical evidence and unmet medical need(s)
- Number of patients (overall population, targeted population, sub-populations)
- Analysis of cost factors (medication, home care, therapy, etc.)
- Overview of economic situation of the cost/benefit and budgetary impact of the compound
- Gap analysis

In a second step, activities will be defined in order to handle and address potential deviations and other critical issues with regulators and the national Market Access institutions.

Task 7.4 **Strategy for price negotiations and reimbursement approval**

The successful development of a pricing and reimbursement strategy (and its tactical elements) requires Market Access insights **and** a clear information on the results of the clinical development programme (efficacy, safety, sub-group benefits, etc.) plus comprehensive understanding of the Market Access environments.

The WP leader will elaborate on a P&R strategy alongside the clinical development using predefined target scenarios for the product profile as an initial proxi. These scenarios will be optimised when final evidence is available.

The questions addressed include:

- Reimbursement opportunities and threats
- Pricing comparisons
- Development of a draft strategy
- GAP-Analysis

Deliverables (brief description and month of delivery)

7.1 Joint scientific advice from National Health Authority (M11)

7.2 Parallel scientific advice from European Medicines Agency and EUnetHTA (M19)

7.3 Market Access landscape overview report (M30)

7.4 Preliminary Market Access Plan (M36)

7.5 Preliminary pricing and reimbursement plan (M44)

About the Health-2-Market project

Health-2-Market is a 3-year long Coordination and Support Action, funded by the Seventh Framework Programme of the European Commission (Cooperation programme – Health theme, Grant Agreement No 305532), aiming at providing training and individual support to health and life science researchers in the process of transforming their research results into successful new business ideas. The duration of the project was 36 months (September 2012 – August 2015).

A portfolio of high-level services, training actions and tools were designed and offered free of charge (some of them are still available), escalating to address the needs of all potential target groups (health/life science researchers, European health research institutes, Technology Transfer Organisations, EU health-related companies and entrepreneurs, health/life sciences European networks, NCPs, etc.) A brief description of Health-2-Market services and assets developed during the project is presented below:

Health-2-Market trainings
17 Seminars and 7 academies free of charge for more than 600 participants

From October 2013 to July 2015, two types of trainings were offered free of charge by Health-2-Market: Weeklong highly intensive international business academies and 1-2 days regional training seminars to highly motivated health/life sciences researchers, entrepreneurs and technology transfer professionals on various topics. Several seminars were co-organised with or hosted by external partners such as higher education and research institutions, technology transfer structures and private companies in the field of health/life sciences, without extra fee-payment. For more info, statistics, testimonials and photos please visit http://www.health2market.eu/results/.

Health-2-Market academies at a glance

- **7 Academies**
- **177 Participants**
- **4 European cities**
  Sophia-Antipolis (FR), Gothenburg (SE), Madrid (ES), Rome (IT)
- **3 training topics**

Health-2-Market seminars at a glance

- **17 seminars (including 1 webinar)**
- **511 Participants**
- **11 European cities**
  Stockholm (SE), Madrid (ES), Sophia- Antipolis (FR), Thessaloniki (GR), Berlin (DE), Budapest (HU), Nicosia (CY), Naples (IT), Athens (GR), Gothenburg (SE), New Castle (UK), Braga (PT), Craiova (RO), Lisbon (PT), Rome (IT)
- **8 training topics**
- **8 co-organisers/ hosts**
  - Bayer HealthCare Pharmaceuticals
  - Cyprus Institute of Neurology and Genetics
  - National Cancer Institute Fondazione G. Pascale
  - Hellenic Pasteur Institute
  - RTC North
  - Creating Health- Research and Innovation funding, Institute of Health Sciences of the Universidade Catolica Portuguesa
  - Startup Braga
  - University of Craiova, Faculty of Physical Education and Sport, Kinetotherapy and Sport Medicine Department (Kinetoterapy - MedicinaSportiva)

Health-2-Market e-learning courses on “bringing research to market”

A valuable e-training web-platform was developed during the project and it is available free of charge on http://elearning.health2market.eu/, providing knowledge on a broad range of topics revolving around three thematic areas. E-learning courses constitute a valuable tool for researchers, aspiring entrepreneurs and start-ups in the field of health/life sciences and an educational opportunity for technology transfer officers, incubators staff, etc. Up to now, more than 400 active users benefit from Health-2-Market e-learning courses. E-learning courses are also accessible on smartphones –both IOS and Android – through the free of charge mobile Health-2-Market application, available on Google Play and the Apple Store.

Health-2-Market advanced services- Individually tailored commercialisation services

A significant offer of Health-2-Market was the provision of twenty, free of charge advanced services which were individually tailored commercialisation services to selected health research projects to help researchers move their cases and ideas a concrete step further towards successful commercialisation. Eight different services were offered, designed such as to cover different phases in the process of commercialisation of a research project. All cases were performed by experts of the Health-2-Market project consortium. For more info and testimonials, please visit http://www.health2market.eu/results.

MOOC on "Roadmap to Entrepreneurial Mind-set and Toolkit," available on Udemy

In the aim of disseminating the educational and training benefits of the Entrepreneurship and Business Planning Venture Academy (hosted by SKEMA Business School), a MOOC (massive open online course) was developed that reflects the combination of both the Venture Academy curricula and the Health-2-Market e-learning offer: https://www.udemy.com/entrepreneurial-mindset-and-toolkit/#/. Although the course has been developed with a health sciences focus, it is open to any researcher, coach and professional interested in grasping a better understanding of business opportunity development in the life sciences environment. Health-2-Market e-learning: http://elearning.health2market.eu/

Support tools for researchers and entrepreneurs for Horizon 2020

A step-by-step guide on innovation strategy in R&D projects

The need for such a free downloadable step-by-step guide was expressed by the participants of **Health-2-Market** activities, as it is not enough to start thinking about innovation strategy and exploitation roots at the end of an R&D project, in fact the process should be understood from the early stage of work. With the contribution of 18 project experts from all over Europe, the **Health-2-Market** team designed the guide to explain why and when the innovation strategy is required in R&D projects, and how it should be developed and implemented. It is intended for a large audience since the topics addressed (commercialisation paths, business models or marketing strategy) are also relevant to many sectors. The guide is available at http://health2market.eu/results/step-by-step-guide

Annotated template (this document) "*Set of good practices to understand and write innovation related issues in Horizon 2020 proposals*"

This guide gives hands-on advice on how to adapt a business model to a Horizon 2020 proposal, taking as a basis the standard application template of the European Commission of Research and Innovation Actions. With comments from innovation experts and R&D exploitation specialists, the guide specifically focuses on sections in which business aspects should be explained in more details. The document is available free of charge on http://www.health2market.eu/results/h2020-annotated-template and Health-2-Market mobile application. If you want to find out more, visit http://www.health2market.eu or download from Google Play or the Apple Store the free of charge Health-2-Market mobile application.

The Health-2-Market project has been implemented by a consortium of 10 partners.

PROJECT PARTNERS

COORDINATOR

INNO AG

PARTNERS

ie university · UNIVERSITY OF GOTHENBURG · skema · engage · APRE · Q-PLAN · WhiteResearch · europa media · INNO TSD

ARIaT - Horizon 2020 Annotated Research and Innovation actions Templates

Innovation dimension in Horizon 2020 proposals:
Set of good practices to understand
and write innovation related issues both
in Research and Innovation Actions (RIA)
and Innovation Actions (IA).

Health 2 Market
FROM HEALTH RESEARCH TO BUSINESS

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