Cross-cutting items

Clinical studies

Applicability and Definition

A 'clinical study' is … any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients/subjects. It includes but is not limited to clinical trials in the sense of the EU Clinical Trials Directive (2001/20/EC).

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Template for clinical studies in SC1 (I)

Purpose

- Providing structured information to experts for evaluation

- Giving applicants the chance to provide detailed information about clinical studies without page limitations
  Reasons:
  - ✓ Detailed but important information, e.g. about Scientific Advice Meetings, in-/exclusion-criteria, etc.
  - ✓ Potentially high number of studies

- Providing necessary information to request 'unit costs'

- Available under 'call documents'[1] and in submission system

[1] e.g.: http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-phc-2015-single-stage_rtd/1632634-essential_information_for_clinical_studies_2015callsv3_01122014_en.pdf

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Template for clinical studies in SC1 (II)

Scope

- Essential information – based on a generic Clinical Study Protocol

- When information is currently not available *(e.g. a clinical study is planned for a later stage of the project and will be based on data of previous studies)* the source of required data should be provided and / or the selection of the applied methodology should be described

- Each section must be shortly and concisely described. In case one or more issues do not apply to a particular study, please briefly explain/justify

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Mandatory deliverables

1. 'First study subject approvals package',
   - ✓ Final version of the study protocol
   - ✓ Registration number of clinical study
   - ✓ Regulatory and/or ethics approvals
2. 'All approvals package', all further approvals
3. 'Midterm recruitment report', 50% recruitment
4. Report on status of posting results in the study registry(s), result posting

Detailed information

about

The template, unit costs, status recruitment sites, subcontracting, mandatory deliverables
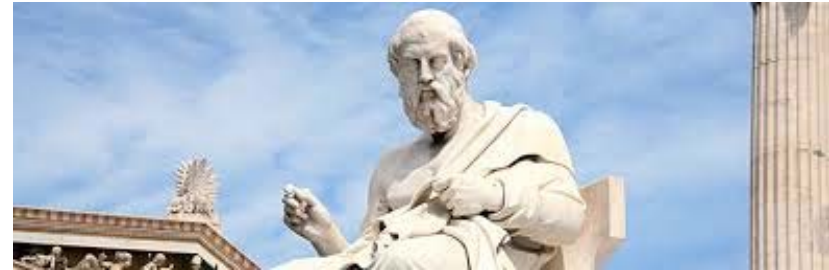
Provided on the Info Day web-site

(Full presentations about clinical studies in H2020 projects can be requested via NCPs)

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Cross-cutting items

Social sciences and humanities (SSH)

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Why SSH in SC1

- Social Sciences investigate the processes that govern the behaviours of individuals and groups

- Humanities and Social Sciences are a **key part of the research and innovation spectrum** and it is important they are integrated in research and innovation programmes

- Health and wellbeing **cannot be achieved by health and medical research alone**

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How to include / assess SSH

- Some specific SSH areas that might be considered for health research are: **ethics, vulnerability, inequality and legal matters**

- SSH needs to be initiated upstream, and not simply considered as an add-on => Help achieving impact through SSH

- Important to check: a) the level of interaction between STEM and SSH; b) the level of rigour of application of SSH c) and, in the scope, the areas that go beyond health economics

- Evaluators → look for evaluators who have a broader knowledge (economics, statistics, psychology, anthropology and behavioural science)

- Importance to disseminate more information on good practices in embedding SSH

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Examples in health research (1)

The variability between patients in responses to the same treatment is one of the most challenging health care problems:

➢ Need to unravel the mechanisms of how peoples' expectations affect immune and endocrine responses and related health outcomes, through the use of multidisciplinary methods in experimental studies (Social Sciences, Biomedical and Life Sciences, Neuroscience and Humanities)

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Examples in health research (2)

How healthy ageing individuals manage to stabilise their quality of life and health in real life:

➢ To examine the determinants of healthy instead of ill ageing and the factors stabilising instead of declining health, through evidence standard for real life instead of laboratory outcomes, with results on the level of individuals instead of populations (gerontology, clinical and experimental psychology, ethnology, psychotherapy, robotics)

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Cross-cutting items

International cooperation

Global challenges call for global responses

- Engaging in international cooperation is essential to attract talent, access knowledge and markets, thus increasing EU competitiveness

- Horizon 2020 is a vehicle to work together with the best worldwide

International Cooperation Strategy

Enhancing and focusing EU international cooperation in research and innovation

European Commission

Horizon 2020
Open to the World

General opening

Horizon 2020 is fully open to participation of entities from across the globe

Targeted opening

Many topics are flagged as being specifically relevant for international cooperation, identifying upfront the targeted area and partner country or region

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Multi-lateral health research activities

IRDiRC
INTERNATIONAL
RARE DISEASES RESEARCH
CONSORTIUM

www.irdirc.org/

InTBIR
International Initiative for
Traumatic Brain Injury Research

http://intbir.nih.gov/

IHEC
International Human Epigenome Consortium

http://ihec-epigenomes.org/

GACD
GLOBAL ALLIANCE FOR CHRONIC DISEASES
AN ALLIANCE OF HEALTH RESEARCH FUNDERS

www.gacd.org/

GloPID-R

Global Research
Collaboration for Infectious
Disease Preparedness

http://www.glopid-r.org/

International
Cancer Genome
Consortium

https://icgc.org/

Global Genomic
Medicine Collaborative

http://www.iom.edu/Activities/Research/GenomicBasedResearch/Innovation-Collaboratives/Global_Genomic_Medicine_Collaborative.aspx

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SC1 and international cooperation

- Reference to specific multi-lateral initiatives

- Mutual opening of research programmes with Third Countries (US)

- Funding of Third Countries entities by their own funding agencies for participating to Horizon 2020 (Switzerland, Australia)
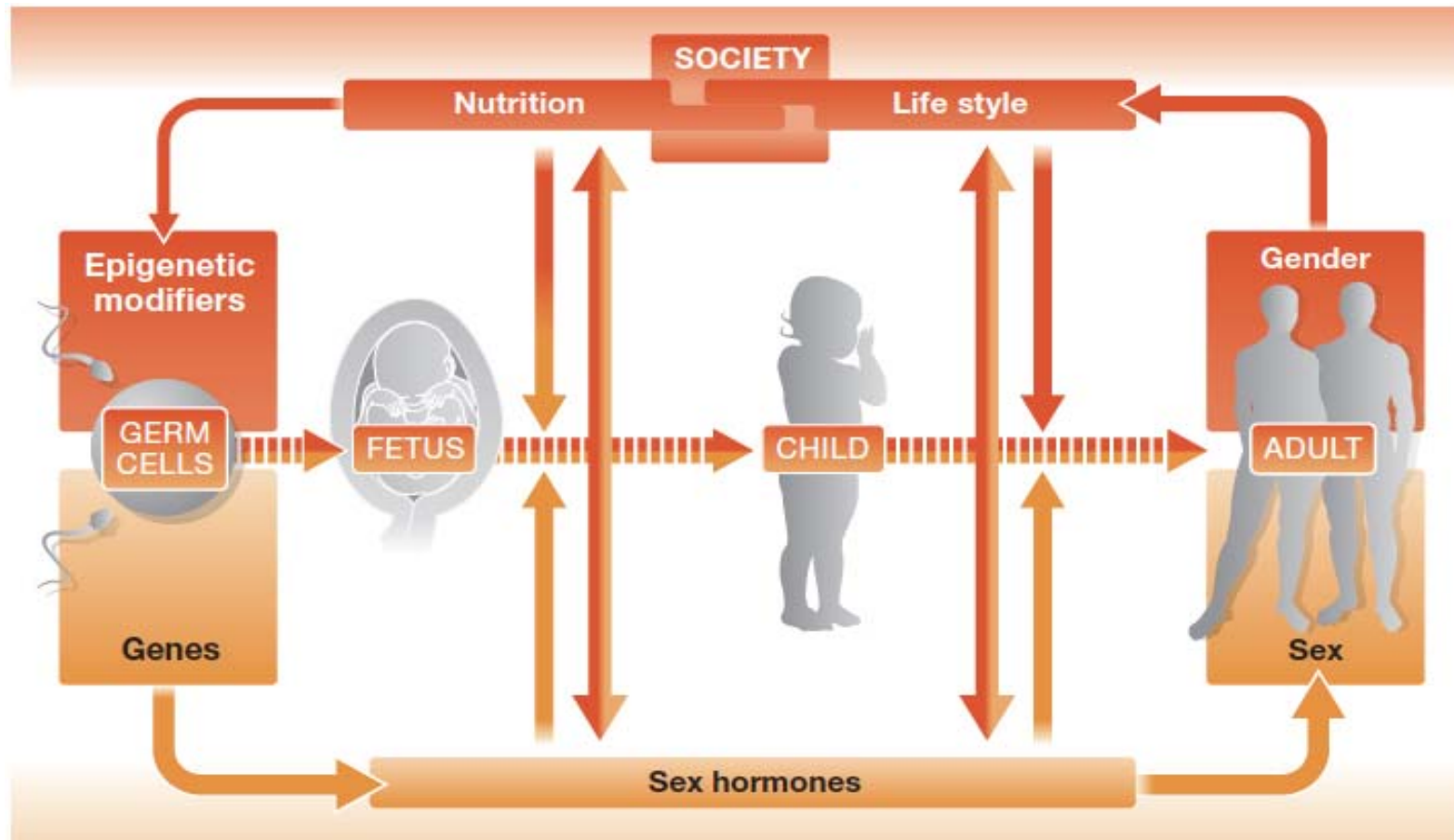
- Specific actions

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Cross-cutting items

Gender

Sex and Gender interact

Regitz-Zagrosek, V. (2012). Sex and Gender Differences in Health. EMBO Reports, 13 (7): 596- 603

Cross-cutting items

Communication

Communicating H2020 projects

Increased importance of communication

- Communication plan and work package in the proposal and the grant agreement (GA **article 38.1**)
- Promote your project and its results beyond the projects own community
- Communicate your research in a way that is understood by non-specialist, e.g. the media and the public
- Inform EC/ Agency in advance of communication activities expected to have a major media impact

Communication ≠ Dissemination

Dissemination (GA article 29) is a separate obligation (e.g. through scientific articles and conferences)

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Guidance

- Start at the outset, continue through entire lifetime

- Plan strategically

- Identify and set clear communication objectives

- Target audiences beyond own community

- Choose pertinent messages

- Use the right medium and means

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Good communication

Horizon 2020 Annotated Grant Agreement

Brochure "Communicating EU Research & Innovation - Guidance for project participants"

http://ec.europa.eu/research/participants/data/ref/h2020/other/gm/h2020-guide-comm_en.pdf

Cross-cutting items

Ethics

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Ethics

- Ethics issues to be carefully considered in proposals

- Check on EU guiding principles

- Ethics evaluation of all proposals included in priority lists

- Ethics requirements to be implemented in funded projects

HORIZON 2020

Thank you
for your attention

Find out more:
www.ec.europa/research/horizon2020
http://ec.europa.eu/research/participants/portal/desktop/en/home.html

HORIZON 2020