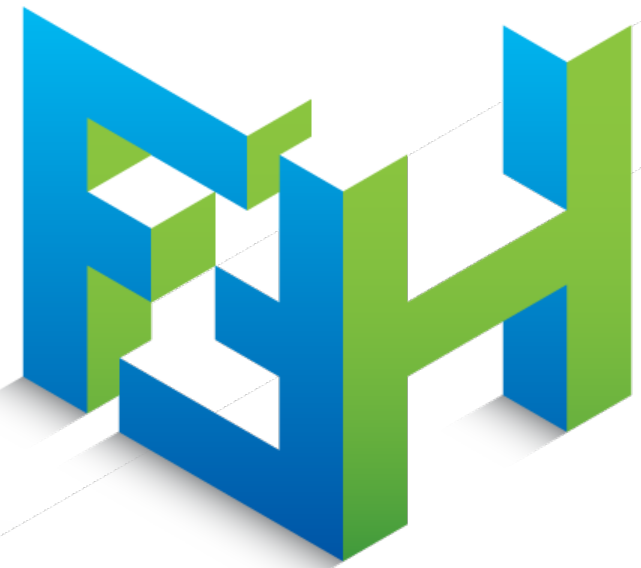


# Fit for Health 2.0

Support to SMEs & Researchers in FP7 and Horizon 2020 health-oriented projects

## Webinar on third parties in Horizon 2020



[www.fitforhealth.eu](http://www.fitforhealth.eu)

03.02.2016 |

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Fit for Health is funded by  
the European Commission

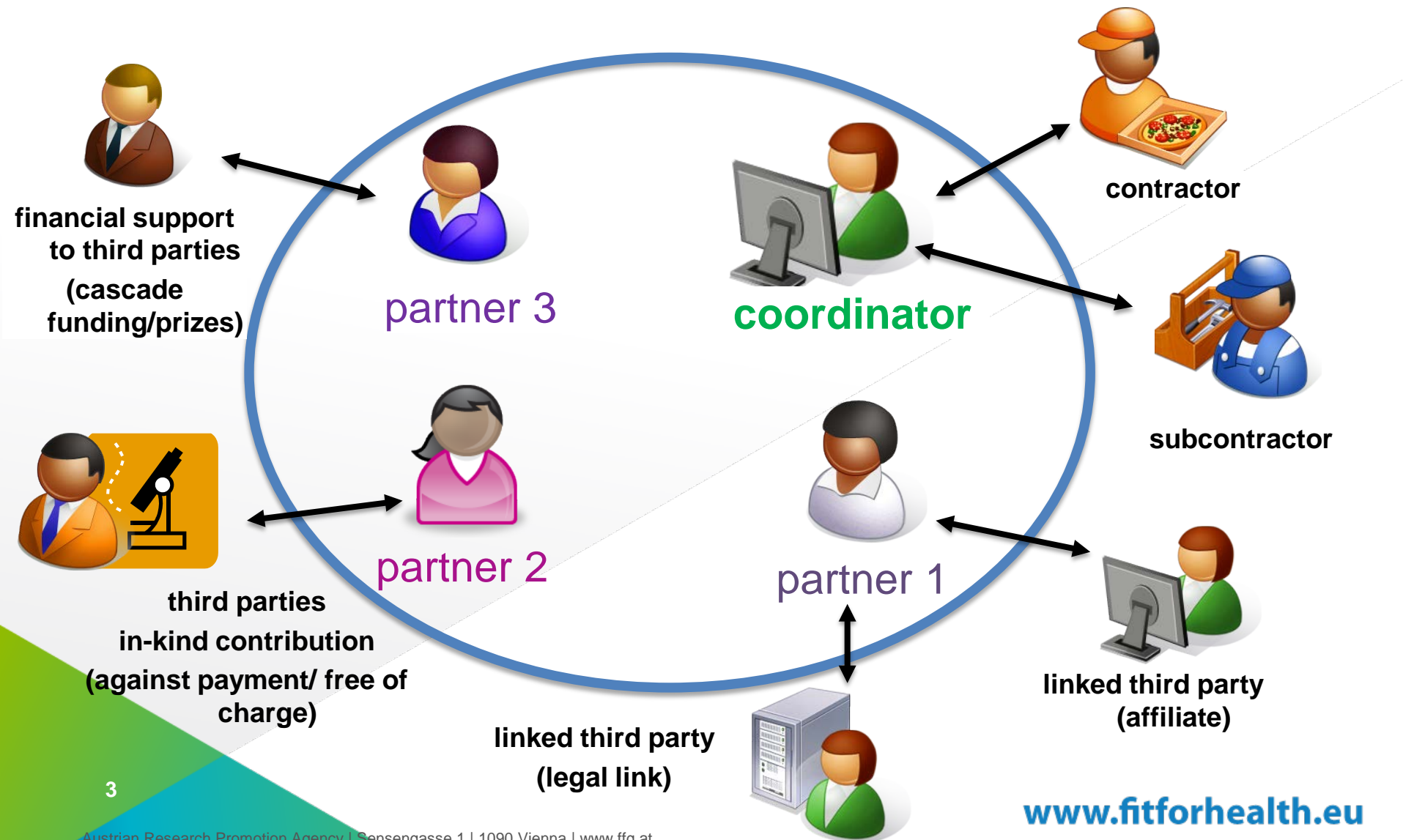
[www.fitforhealth.eu](http://www.fitforhealth.eu)



## OVERVIEW

- ✓ **What is a ,third party‘ in Horizon 2020?**
- ✓ Types of third parties
- ✓ How to involve contract research organisations (CROs)
- ✓ Third parties further issues

# OVERVIEW THIRD PARTIES IN HORIZON 2020



## OVERVIEW

- ✓ What is a ‚third party‘ in Horizon 2020?
- ✓ **Types of third parties**
- ✓ How to involve contract research organisations (CROs)
- ✓ Third parties further issues

## THIRD PARTIES INVOLVED IN THE PROJECT

- Contractors providing goods, works or services (Art. 10 GA)
- Subcontractors (Art. 13 GA)
- Linked third parties (Art. 14 GA)
- Third parties providing in-kind contributions
  - against payment (Art. 11 GA)
  - free of charge (Art. 12 GA)
- Financial support to third parties (cascade funding/prizes Art. 15 GA)

# COSTS OF SERVICES I

## Definition of a service:

- based on a **contract for services** which is **not** identified in **Annex 1** of the GA as an **action task**
- form of costs => **‘other direct costs’**

Art.  
10 GA

## Examples:

- consulting costs (e.g. IPR)
- translation costs
- catering
- printing costs
- costs of a certificate on the financial statements (CFS)

## COSTS OF SERVICES II

Eligibility conditions:

- best price-quality ratio or lowest price
- compliance with national procurement rules

## COSTS OF SERVICES III

### Please note:

- costs of services are taken into account for the application of the flat-rate for indirect costs
- **responsibility** for the work lies fully with the **beneficiary**
- service contracts should foresee that **intellectual property** generated by the contractor reverts to the beneficiary
- consider conditions in case of existing framework contracts



# SUBCONTRACTING I

## Definition of a subcontract:

- A 'subcontract' means the **purchase of goods, works or services** that are identified in **Annex 1** of the GA as **action tasks**.

A pink, rounded rectangular callout box with a blue border, containing the text 'art. 13 GA'.

art.  
13 GA

### Examples:

- building a prototype, *if described in Annex 1 as action task*
- conducting a survey, *if described in Annex 1 as action task*
- analytical work, *if described in Annex 1 as action task*

# SUBCONTRACTING II

## Characteristics of a subcontractor:

- receives an **order** and issues an **invoice**
- charges a price which usually includes a **profit** (no-profit rule does not apply)

## SUBCONTRACTING III

### Eligibility conditions:

- **best price-quality ratio or lowest price**
- compliance with national procurement rules
- tasks to be implemented and estimated costs must be set out in Annex 1 of the GA
- simplified approval procedure for new subcontracts at the full discretion of the EU Commission/Agency

## SUBCONTRACTING IV

### Please note:

- costs of subcontracts are **not** taken into account for the application of the flat-rate for indirect costs
- **responsibility** for the subcontracted work lies fully with the **beneficiary**
- subcontracts should foresee that the **intellectual property** generated by a subcontractor reverts to the beneficiary
- subcontracting to affiliates is **only allowed in exceptional cases** (framework contract; affiliate is the usual provider)
- subcontracting **between beneficiaries** is **not allowed** in the **same GA**

## SUBCONTRACTING OF 'PARTS OF TASKS'?

We are afraid it is not possible to give a conclusive answer to your question since the reply would depend, at least partially, on the specific case. For example, let's suppose that the **action task** described in **Annex 1** is to **carry out 1000 laboratory tests**. The **consortium carries out directly 500** but decides to **externalise the other 500**. This would be a **subcontract** even if the "full task" has not been implemented by the external service provider.

[https://www.ffg.at/sites/default/files/downloads/service/h2020-faq\\_res\\_stand\\_2016-01-28.pdf](https://www.ffg.at/sites/default/files/downloads/service/h2020-faq_res_stand_2016-01-28.pdf)

## SUBCONTRACTING OF ,PARTS OF TASKS‘?

Another example might be the **development of a prototype** identified as an **action task** in Annex 1. Let's suppose that this prototype is **composed of several elements** among which there is a **tailor-made stainless steel container** and a **new electronic device that needs to be designed and fabricated** to be integrated in the prototype. If these two elements are externalised, the tailor-made stainless steel container would be normally considered as a **purchase of goods** needed for the action task (developing the prototype). In contrast, designing and fabricating the new electronic device would be **considered as subcontracting** as it is **part of the action task (developing the prototype)**.

As you can see, if it is the entire "task" or only "part of the task" what is externalized does not determine in itself if this is to be regarded as a subcontract or as a purchase of goods or services.

[https://www.ffg.at/sites/default/files/downloads/service/h2020-faq\\_res\\_stand\\_2016-01-28.pdf](https://www.ffg.at/sites/default/files/downloads/service/h2020-faq_res_stand_2016-01-28.pdf)

# DIFFERENCES SUBCONTRACTS AND CONTRACTS TO PURCHASE SERVICES

subcontracts	contracts for services
concern the implementation of action tasks (as are described in Annex 1)	do not concern action tasks, but they are necessary to implement action tasks by beneficiaries
must be indicated in Annex 1	do not have to be indicated in Annex 1
to be declared as 'direct costs of subcontracting'	to be declared as 'other direct costs'
no indirect costs	25 % indirect costs
<p style="text-align: center;">best price-quality ratio or lowest price responsibility for the work lies fully with the beneficiary</p>	

## THIRD PARTIES INVOLVED IN THE PROJECT

- Contractors providing goods, works or services (Art. 10 GA)
- Subcontractors (Art. 13 GA)
- **Linked third parties (Art. 14 GA)**
- Third parties providing in-kind contributions
  - against payment (Art. 11 GA)
  - free of charge (Art. 12 GA)
- Financial support to third parties (cascade funding/prizes Art. 15 GA)



# LINKED THIRD PARTIES I

## Who can be a ,linked third party‘?

art.  
14 GA

Only

- ,**affiliated** entities‘ (Art. 2.1(2)RfP)

and

- ‘entities with a **legal link** to a beneficiary’

## LINKED THIRD PARTIES II

Legal link = established relationship which is:

- ❖ broad and not specifically created for the work in the action
  - duration must go beyond the action duration
  
- ❖ legal relationship
  - legal structure (e.g. relationship between members of an association) or agreement/contract (e.g. collaboration agreement for research)

e.g. Joint Research Units; associations, foundations or other legal entities composed of members.

## LINKED THIRD PARTIES III

The entity carrying out the majority of the work should be the beneficiary.

## LINKED THIRD PARTIES IV

### Eligibility conditions:

- **linked third parties** and the **tasks to be implemented** by them must be set out in **Annex 1** of the GA
- **same eligibility conditions** as for beneficiaries apply

## LINKED THIRD PARTIES V

Please note:

- responsibility for the work lies with the beneficiary
- linked third parties declare their **own costs** in their **own financial statement**
- the Commission/Agency may require joint and several liability of a linked third party

# DIFFERENCES BETWEEN (SUB)- CONTRACTS AND LINKED THIRD PARTIES

subcontracts + contracts for services	linked third parties
(more) financially motivated	(more) motivated by reasons of content
contractual link with the beneficiary	link with the beneficiary: affiliated entity or legal link not limited to the action
the eligible costs are the (market) prices charged to the beneficiary	the eligible costs are the costs of the linked third party (no profit; conditions for eligibility of costs apply)
responsibility for the work lies fully with the beneficiary	

## THIRD PARTIES INVOLVED IN THE PROJECT

- Contractors providing goods, works or services (Art. 10 GA)
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- Linked third parties (Art. 14 GA)
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# OVERVIEW IN-KIND CONTRIBUTIONS

A **Third Party provides in-kind contributions** to a beneficiary  
(but is **not** otherwise **involved** in the project)

in-kind contributions may be provided

- free of charge or
- against payment

→ only the **actual costs** of the in-kind contribution are eligible (**no profit margin**)

examples:

seconded personnel

use of equipment / research infrastructure



## IN-KIND CONTRIBUTIONS BY THIRD PARTIES (AGAINST PAYMENT)

→ beneficiaries may declare their costs up to the costs actually incurred by the third party

art.  
11 GA

Eligibility conditions:

- **third parties, in-kind contributions** and **estimated costs** must be set out in **Annex 1** (simplified approval procedure for new in-kind contributions at the full discretion of the EU COM/Agency)
- only the **actual costs** of the third party are eligible (**no unit costs** except unit costs for conducting clinical studies)

## IN-KIND CONTRIBUTIONS BY THIRD PARTIES (FREE OF CHARGE) I

art.  
10 GA

- the costs of the third party may be declared as eligible costs **although** there is no cost incurred by the beneficiary
- **if given specifically to be used for the project**, the in-kind contributions have to be declared as **receipts**

## IN-KIND CONTRIBUTIONS BY THIRD PARTIES (FREE OF CHARGE) II

art.  
10 GA

Eligibility conditions:

- costs must be recorded in the *accounts of the third party*
- **third parties, in-kind contributions** and **estimated costs** must be set out in **Annex 1** of the GA (or amendment/simplified approval procedure)
- only **actual costs** of the third party are eligible (**no unit costs**) **except unit costs** for conducting **clinical studies**)

# INDIRECT COSTS OF IN-KIND CONTRIBUTIONS

The eligibility of indirect costs depends on where the in-kind contributions are used:

## a) on the premises of the beneficiary:

- indirect costs are incurred by the beneficiary  
=> beneficiary receives the **regular flat-rate of 25%**

# INDIRECT COSTS OF IN-KIND CONTRIBUTIONS

The eligibility of indirect costs depends on where the in-kind contributions are used:

## b) on the premises of the third party:

- indirect costs are incurred by the third party  
=> **direct costs** actually incurred by the third party; may be **increased by a flat-rate of 25%** on these costs
- therefore, the costs of the in-kind contribution are **not** taken into account when calculating the indirect costs of the beneficiary

## THIRD PARTIES INVOLVED IN THE PROJECT

- Contractors providing goods, works or services (Art. 10 GA)
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## FINANCIAL SUPPORT TO THIRD PARTIES (CASCADE FUNDING/PRIZES)(ART. 15 GA)

- financial support' is given via a financial donation to natural or legal persons

e.g.: allowances, scholarships, fellowships, non-repayable financial assistance to local NGOs, seed money to start-ups, microcredit, prizes (not to be confused with 'EU prizes')

## FINANCIAL SUPPORT TO THIRD PARTIES (CASCADE FUNDING/PRIZES)(ART. 15 GA)

- financial support may also be provided by a linked third party
- optional article - only where **explicitly allowed in the work programme/call**
- **Danger of confusion:** do not enter 'costs of linked third parties' in budget column for 'costs of financial support to third parties'



Types of third parties	CHARACTERISTICS						
	Does work of the action	Provides resources or services	What is eligible?	Must be indicated in Annex 1	Indirect costs	Selecting the third party	Articles
<b>Linked third party</b>	<b>YES</b>	<b>NO</b>	<b>Costs</b>	<b>YES</b>	<b>YES</b>	Must be affiliated or have a legal link	<b>Article 14</b>
<b>Subcontractors</b>	<b>YES</b>	<b>NO</b>	<b>Price</b>	<b>YES</b>	<b>NO</b>	Best value for money, avoid conflict of interest	<b>Article 13</b>
<b>Third party providing in-kind contributions</b>	<b>NO</b>	<b>YES</b>	<b>Costs</b>	<b>YES</b>	<b>YES</b>	Cannot be used to circumvent the rules	<b>Articles 11 and 12</b>
<b>Contractors</b>	<b>NO</b>	<b>YES</b>	<b>Price</b>	<b>NO</b>	<b>YES</b>	Best value for money, avoid conflict of interest	<b>Article 10</b>
<b>Financial support to third parties</b>	<b><u>Only if allowed in the call</u></b> The beneficiaries' activity consists in providing financial support to the target population			<b>YES</b>	<b>NO</b>	According to the conditions in Annex 1	<b>Article 15</b>

## OVERVIEW

- ✓ What is a ‚third party‘ in Horizon 2020?
- ✓ Types of third parties
- ✓ **How to involve contract research organisations (CROs)**
- ✓ Third parties further issues

# CLINICAL CENTRES

Clinical centres whose contribution is limited to subject recruitment or treatment may have status of:

- Full beneficiary (always preferred)

## CLINICAL CENTRES

If obstacles to become beneficiary (or linked third party) =>

1. Use of **in-kind contributions** provided by **third parties against payment** (Art. 11 GA)
  - ✓ requires prior agreement with beneficiary – prior to start of work, not necessarily prior to signature of GA
  - ✓ agreement might be specific to project
2. **Subcontractor** (Art. 13 GA)
  - ✓ agreed 'price per patient/subject'

Not possible to reimburse  
recruitment sites based on **Article 10 GA.**

## CONTRACT RESEARCH ORGANISATIONS

- If subcontracting only limited part of the action can be sub-contracted (Art. 13 GA)
- Existing academic CROs (e.g. ECRIN network) might be willing to become beneficiary
- Commercial CROs usually work 'for profit' => COM will consider accepting subcontracting

Not possible to reimburse  
CROs based on **Article 10 GA.**

# CONTRACT RESEARCH ORGANISATIONS SUBCONTRACTING

- **Clinical study is the main activity of the project:**
  - Core study expertise cannot be subcontracted, but certain parts (GMP manufacturing, monitoring etc.) might be subcontracted as long as general regulatory expertise is available and the study design, high-level study management and oversight remain as tasks within the consortium (budget share: not essential criterion!)
- **Clinical study is just a small part of the project:**
  - (i.e. most of the project is preclinical activity) => study might be subcontracted in its entirety

## OVERVIEW

- ✓ What is a ‚third party‘ in Horizon 2020?
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- ✓ **Third parties further issues**

# PROJECT PROPOSAL I

- ✓ consider if subcontractors and/or other third parties shall be involved in the project
- ✓ explain planned involvement of third parties in the proposal



## PROJECT PROPOSAL III

### 4.2. Third parties involved in the project (including use of third party resources)

*Please complete, for each participant, the following table (or simply state "No third parties involved", if applicable):*

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y/N
<i>If yes, please describe and justify the tasks to be subcontracted</i>	
Does the participant envisage that part of its work is performed by linked third parties <sup>1</sup>	Y/N
<i>If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party</i>	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	Y/N
<i>If yes, please describe the third party and their contributions</i>	

## PROJECT PROPOSAL II

- ✓ general conditions for participation and funding apply to linked third parties (e.g. 100% funding rate for non-profit legal entities in IA) – attention in case of third countries
- ✓ estimated budget => separate column for ‚financial support to third parties‘ – other costs of third parties are to be presented under the ‚regular‘ costs of the beneficiary

# BUDGET FOR THE FULL PROPOSAL

## Research and Innovation actions

No	Participant	Country	(A) Direct personnel costs/€	(B) Other direct costs/€	(C) Direct costs of sub-contracting/€	(D) Direct costs of providing financial support to third parties/€	(E) Costs of in-kind contributions not used on the beneficiary's premises/€	(F) Indirect Costs / € (=0.25(A+B-E))	(G) Special unit costs covering direct & indirect costs / €	(H) Total estimated eligible costs / € (=A+B+C+D+F+G)	(I) Reimbursement rate (%)	(J) Max. EU Contribution / € (=H*I)	(K) Requested EU Contribution / €
1			0	0	0	0	0	0,00	0	0,00	100	0,00	0,00
Total			0	0	0	0	0	0,00	0	0,00		0,00	0,00

## Innovation actions

(H) Total estimated eligible costs / € (=A+B+C+D+F+G) (Beneficiary)	(I) Reimbursement rate (%) (Beneficiary)	(J) Max. EU Contribution / € (=H*I) (Beneficiary)	(K) Costs of third parties linked to participant (Third parties)	(L) Max. EU Contribution / € (Third parties)	(M) Total Costs for (beneficiary + third parties) (=H+K)	(N) Max. EU Contribution / € (beneficiary + third parties) (=J+L)	(O) Requested EU Contribution / €
0,00	100	0,00	0	0	0,00	0,00	0,00
0,00		0,00	0,00	0,00	0,00	0,00	0,00

# GRANT PREPARATION

- ✓ every **linked third party** needs a **validated PIC**
- ✓ each beneficiary must enter the PIC of the linked third parties associated with it in the participant portal

# THIRD PARTIES IN CONSORTIUM AGREEMENTS



## 4.3 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties ... in the Project remains responsible .... for **such third party's compliance with the provisions of this Consortium Agreement** and of the Grant Agreement. It has to **ensure** that the **involvement of third parties does not affect the rights and obligations of the other Parties** ...

### **Please consider:**

- liability issues
- compensation for damages
- confidentiality issues

... between the beneficiary and its third parties

# COST REPORTING

- information on subcontracting is required in the financial reports
- **personnel seconded against payment**: to be declared under personnel costs
- **only linked third parties** fill in their **own financial statement** (and need a certificate on the financial statements, if the linked third party's costs are above the CFS threshold)

# PARTICIPANT PORTAL

Third parties **do not have project roles** in the **participant portal** (PP), since they are not parties to the grant agreement.

Financial statements of linked third parties:

- linked third parties do not have access to the project in the participant portal and do not have an **LSIGN** for the project



# PARTICIPANT PORTAL



Financial statements of linked third parties =>

- either the beneficiary fills in the financial statement for the linked third party
- or
- assigns the role ‚task manager‘ to a representative of the linked third Party (other roles are not normally recommended)





# CALCULATION OF THE FLAT RATE FOR INDIRECT COSTS

Flat-rate of 25% of the eligible direct costs, from which are excluded

**...in all projects:**

- costs of **subcontracting**
- costs of **in-kind contributions provided by third parties** which are **not used on the beneficiary's premises**

## CALCULATION OF THE FLAT RATE FOR INDIRECT COSTS

Flat-rate of 25% of the eligible direct costs, from which are excluded...

**...only in case of an OPTION in the GA:**

- financial support to third parties (art. 15 GA)

# CONTROLS REGARDING THIRD PARTIES

- all types of third parties may be **subjected to controls** (checks, reviews, audits and investigations) by the EU commission, EU agencies, EU court of auditors and OLAF
- for this purpose, **third parties** must **allow access to their premises** and provide the requested **information** and data

see:

- article 22: checks, reviews, audits and investigations
- article 23: evaluation of the impact of the action

# CONTROLS REGARDING THIRD PARTIES

- ✓ **Attention:** ensure that the **EU can exercise its control rights** vis-a-vis third parties by **including appropriate clauses** in all contracts with third parties

## FURTHER INFORMATION

### **General Grant Agreement:**

[http://ec.europa.eu/research/participants/data/ref/h2020/mga/gga/h2020-mga-gga-multi\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/mga/gga/h2020-mga-gga-multi_en.pdf)

### **Annotated Grant Agreement Article 8, 10-15:**

[http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/amga/h2020-amga\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf)

### **List of Legal National Contact Points:**

[http://ec.europa.eu/research/participants/portal/desktop/en/support/national\\_contact\\_points.html](http://ec.europa.eu/research/participants/portal/desktop/en/support/national_contact_points.html)

### **Clinical trials in Horizon 2020**

<http://www.fitforhealth.eu/downloads/short-webinar-clinical-trials-h2020-projects>



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