

Andrea Ungersbäck, Project manager AGES/AT





Agenda

- Project description
- General recommendations for coordinators
- Experiences after 1 Year Project coordination
 - Basic concept for 4 mandatory work packages
 - WP1 Coordination / WP2 Dissemination / WP3 Evaluation / WP4 sustainability
- Attachment: Coordinator Toolbox for download
 - Plans, templates & related documents: based on MS Office
 - Project Manual, Risk Management Plan, Quality Management Plan, Financial Management Procedure
 - Stakeholder Analysis/Communication & Dissemination Plan, Evaluation Plan, Sustainability Plan
 - time sheet template, deliverable template, financial report form etc.





Project description: EU4H 11: Joint Action on quality of medicines and implementation of the pharmaceutical legislation/strategy

- Project duration: November 2022 October 2025
- Estimated Budget: 3,43 Mio. EUR
- Participants: **39 National Competent Authorities** / 29 EU/EEA Countries
- Coordinator: AGES/AT (WP1, WP2, WP4 Lead)
- Coordinator supports WP3 and the 3 technical work packages
- Project Steering Committee = deciding body: 4 WP Leaders
- Project activities and main objective: strengthen capacities of NCAs / Medicines Inspectorates (GMP/GDP) and strengthen the EU/EEA Joint Audit Programme, work on/improve/extend related processes, offer trainings and co-financing to NCAs.
 - Harmonised inspection standards / GMP interpretation / confidence between surveillance authorities and cooperation in the field
 - Safe and high-quality medicines







General recommendations for Coordinators I

Project manager

- Service-oriented, solution-oriented, someone who cares with coordination skills
- experienced in the field EU projects or likes to acquire knowledge in new fields
- Basic quality management knowledge / documentation affinity
- Close collaboration with the main technical expert
- Collaboration with legal / financial colleagues (WP1) and communication experts
 i.a. (WP2)
- Exert role actively to coordinate and support their participants, esp. in administrative/financial aspects
 - Clear instructions and support coordinator communicates with project officer
 - Short reaction times

Consortium Agreement

Include GA requirements for Affiliated Entities/Assoc. Partners





General recommendations for Coordinators II

Support or lead WP2 Dissemination Work Package

- Minimum Coordinator contribution: support for documentation
- take over communication about project to the public/media via website, social media accounts
- If possible, take over the lead

Support WP3 Evaluation Work Package

- connection to WP1 contents / support for documentation
- Lead = another organisation

Support or lead WP4 Sustainability Work Package

- Depending on resources/strengths/coordinative skills of technical experts at Coordinator
- No One-Man/Woman-Show broad support

Participate in each technical WP to support and link between WP

- Guidance/assistance in aspects of mandatory WP to ensure implementation according grant agreement provisions
- comprehensive overview, to identify possible issues
- Support in administrative tasks (e.g. surveys) efficiency of JA implementation





General recommendations for Coordinators III

- Consider Pre-phase is not co-financed ~ 6-9 PM until GA signature
- At proposal stage: estimate budget for each budget item / cost category
 - Facilitates budget flexiblity in project implementation
- Stay in contact with HaDEA Project officer + EC/DG SANTE
- Support of Nominating authority
- Liase with experienced coordinators / project managers



Basic concept for 4 mandatory work packages is shared

WP1 Coordination/WP2 Dissemination/WP3 Evaluation/WP4 Sustainability

- Based on our Description of Action/Grant Agreement, but adapted as found beneficial
 - Documents and timelines for first 12 months in mandatory work packages
 - Toolbox: plans and templates slightly advanced
- Useful toolbox: Free PM² methodology of European Commission
- PM² Project Management Methodology (europa.eu)
- Free online logo creators





Coordinator = center for documentation & reporting

WP1
Cont. Reporting EU Portal deliverables/milestones

WP2
Cont. Reporting EU Portal
communication/dissemination
activities

COO
Project Documentation
monitoring of deadlines

Centralisation for efficiency

WP3
Needs data/information
to evaluate





WP1 Coordination – List of Deliverables/Milestones

Deliverable No. and Deliverable Name	Work Package	Due date (month)
D1.1 Project Manual	WP1	M3
D1.2 Risk management plan	WP1	M3
D1.3 Financial management procedure	WP1	M6
D1.4 Quality management plan	WP1	M6
Milestone No. and Milestone Name	Work Package	Due date (month)
MS1 Project start and kick-off meeting	WP1	M2
MS2 Project Manual	WP1	M3
MS3 Financial management procedure	WP1	M6
MS4 Final project meeting	WP1	M36

Keep it as simple as possible, key plans / documents



WP1 experience – some aspects I

Kick-off meeting

- Set deadline to M2 to have enough time to prepare to have a fruitful outcome (if you manage to complete in M1, it's fine ☺)
- Invite your PO to attend and to hold a short presentation (mostly online)
- Part for all participants (online): "Outline" and key information
 - presentation of the project and single WP, important general information (time-recording, admin/financial aspects...)
- Part to work actively by Decision Body (& maybe WP experts) (F2F): Active work
 - discuss aspects of project manual, risks and mitigation measures, indicators/evaluation plan
 - · Maybe first discussions in technical WP

Project manual

- Provide Time sheet template before project start! E.g. Chafea time sheet template
- Template for Deliverables





Risk Management Table

Continuous documentation in Excel file (risks, issues)

	Risk Management Table							
	Comment: content of template (OPM2-23.MC.Log.v3.0.1).Risk_Log.(ProjectName).(dd-mm-yyyy).(vx.x) is used							
	Risk	Identification & Description			Risk As	sessment	t	
Risk ID	Description	Consequences	Identified By Identification Date	Likelihoo d (3=high, 1=low)	Impact (3=high, 1=low)	Risk score	Risk Owner	Strategy (avoid, transfer, mitigate, accept)
R01	Human error risks (loss of documentation, inaccurate reporting)	loss of documentation, inaccurate reporting		1	3	3	coo	mitigate
H02	risk of loss of knowledge due to personnel changes	expert's input lost delayed completion of tasks due to additional briefing/learning phase required with new staff		1	2	2	coo	mitigate

		Trend	Occurence	١			
	Strategy (avoid, transfer, mitigate, accept)	Action Details / Mitigation measures Contingency Plan	WP/Assignee	Tracability / Comments	Risk Score Trend	Date of occurence -> ISSUE	
	mitigate	Communicate to all involved partners the necessity to work accurately Establish a process for tracking and follow up of necessary actions Implement a regular review and reporting process as well as formats for reporting	COO & WP Leads				
NFI urc ire	mitigate	Implement comprehensive knowledge management within the project management Each WP Leader is at least represented by 2 technical experts Regularly circulate information across the project team regular open communication and interaction with staff / TC to monitor progress and status of all WPs, open communication between partners redistribution and sharing of the work between project partners early assignment of tasks	COO & WP Leads				



This presentation is part of the action "NFI which has received funding from the Euro Programme (2014-2020) under grant agre

. Close project monitoring by COO to be defined in quality

Issue Management Table

Continuous documentation in Excel file (risks, issues)

Issue Management Table

Issue ID	Categor y	Description	Consequences	Identified By Identification Date	Relevanc e (1=low; 5=high)	Actions to take / taken	Outcome/Comments	WP/ Assign ee
101					1			
102					2			
103					3			
					4			
					5			
								1



WP1 experience – some aspects II

Quality Management Plan

- Linked to evaluation plan
- monitoring of deadlines & quality (e.g. deliverable review process)
- quality entries (deviations, opportunities for improvements & CAPAs)
- quality control
 - 1 QC check of records supporting the costs declared per participant

Financial Management Procedure

- Budget plan updates
- 6-monthly project-internal financial reports
 - Cumulative internal reporting M6, M12, M18 prior to HaDEA reporting
 - · Personnel costs: based on hours spent
 - Tool for personnel cost calculation & tool for conversion into euros in the report file
- Costs per participant and in total / work package vs. Budget
- Structure files to easily copy/paste/link/excerpt data





WP2 Dissemination – List of Deliverables/Milestones

Deliverable No. and Deliverable Name	Work Package	Due date (month)
D2.1 Project Reports	WP2	M7, M13, M25, M31
D2.2 Dissemination Plan	WP2	M8
Milestone No. and Milestone Name	Work Package	Due date (month)
MS5 Dissemination plan	WP2	M8

- Who is the main target group?
 - Maybe include reporting to special groups as activity/deliverable
- Project Reports at 6-month intervals
 - Opportunity to report regularly to HaDEA about activities done/changes
 - attach budget expenditure per WP and for the Project
 - WP Leaders describe their WP progress

Attach further relevant docs if not listed as deliverable





WP2 experience – some aspects

Dissemination Plan

- Stakeholder Analysis (a.o. process owner for the JA activities (! Maybe "outside"))
- Contribution of WP leaders to disseminate "their" WP results
- Use / complement the plan to document activities

Communication of the Project (public/media/in general)

- Present the JA on your organisations' website or create an own website and/or use social media channels
 - regular updates; use hashtags recommended by HaDEA
- Include EU-Emblem, funding statement, disclaimer
- Share your communication with all participants / guide them to easily follow/link
- **Templates for communication / dissemination** activities (PPT_slides)
 - Include EU-Emblem, funding statement, disclaimer





WP3 Evaluation – List of Deliverables/Milestones

Work Package	Due date (month)
WP3	M4
WP3	M18
WP3	M36
Work Package	Due date (month)
WP3	M4
WP3	M4
	WP3 WP3 WP3 Work Package WP3

- Each WP Leader must actively participate (KPIs for each WP)
- Use / complement the plan to document activities
 - Coordinator ensures data availability
 - WP leader evaluates (no need to start with collecting missing information)



• WP4 Sustainability – List of Deliverables/Milestones

Deliverable No. and Deliverable Name	Work Package	Due date (month)	
D4.1 Sustainability plan	WP4	M12	
D4.2 Update of Sustainability plan	WP4	M32	
Milestone No. and Milestone Name	Work Package	Due date (month)	
MS9 Sustainability plan	WP4	M12	
MS10 Update of Sustainability plan	WP4	M32	

- Technical WP Leaders must support in sustainability
- Linked to dissemination
- Describe surrounding conditions/environment
- Define sustainability work fields and concrete tasks
- Update the plan according to applicability and project results





WP4 experience

- Think about a regular activity to be co-financed that support overall objectives
 - E.g. co-financing of training activities in field XY
 - In case of underspending if budget flexibility applies:
 - You can decide on re-distribution of the budget
 - That's an opportunity to spend unused budget to support further the JA goals
 - You have to describe the action task in your Proposal / Grant Agreement
 - Clarify with EC/HaDEA
 - Equal distribution amongst participants





Estimated budgets

Good estimate for our project

that's the minimum, we will need it all

- WP1 Coordination
 - Project manager / Technical Expert in total 18 PM
 - Administrative personnel 6 PM
- WP2 Dissemination
 - Project manager / Technical Expert in total 18 PM
 - Administrative personnel 6 PM
- WP3 Evaluation (support: COO)
 - Project Manager / Technical expert in total 18 PM
- WP4 Sustainability
 - Project Manager / Technical expert in total 12 PM
 - Administrative personnel 6 PM

Coordinator supports in every technical WP with 3 PM





Thank you

Thanks to experienced project managers at **AGES**Thanks to the Work Packages Leaders **HALMED (HR), ANSM (FR) and NCPHP (HU)** for

their continuous contribution in EU4H 11 JA implementation & agreement to share documents

Thanks to HaDEA and DG SANTE for continuous support

Download link to access our toolbox:

https://nc.ages.at/index.php/s/LNd9FtGgmtH7Tzo

Password: eu4h11!!

Take the opportunity of being a JA coordinator Best case: build up expertise to coordinate regularly

