Joint EU-MNE Programme for
Employment, Education and Social Welfare

Monitoring the prescription of diclofenac
with the aim of optimisation of its safe use
CFCU/MNE/128

Project Handbook

DEV 1.2

April, 2020.

This project is co-funded by
the European Union

The project is implemented by

Program:	Collaborative grant scheme for innovative project ideas
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Project:	Monitoring the prescription of diclofenac with the aim of optimisation of its safe use
Project start date:	16.03.2020.
Project duration:	24 months
Deliverable Number:	D.1.2
Deliverable Leader:	Maja Stanković
Status:	Final
Submission Date:	30.04.2020.
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List of Abbreviations

C&VP	***Communication and Visibility Plan***
EU	***European Union***
PHC	***Primary Health Care***
IT	***Information Technology***
IIHS	***Integral Information Healthcare System***
HCP	***Healthcare Professionals***
HCIs	***Healthcare Institutions***
CALIMS	***Agency for Medicines and Medical Devices***
MoH	***Ministry of Health***
HIF	***Health Insurance Fund***
DoA	***Description of the Action***

Table of Contents

1. INTRODUCTION

1.1. Purpose of this document

This Project Handbook has mainly two functions.

Firstly, it is a reference source for both project partners covering many day-to-day activities.

Secondly, it intends to standardise various elements of the project e.g. communication, project reports, deliverables, etc. through the use of agreed procedures and templates where relevant.

It will be a dynamic document and will be updated as required throughout the project.

1.2. Precedance

The general principles for the project execution are defined in the EU Grant Agreement (GA), the Description of the action (DoA) and the Partnership Agreement on joint project implementation (PA). The Project Handbook does not replace any of these established agreements, nor does it replace any of the EU guidelines for project implementation and documentation.

Where there are any inconsistencies between these documents, the following order of precedence should be applied:

1. EU Grant Agreement including Description of the action, also referred to as the Grant Agreement (EU GA) Annex 1;
2. Partnership Agreement on joint project implementation (PA);
3. Project Handbook (this document).

2. GENERAL PROJECT INFORMATION

Title of the action:	Monitoring the prescription of diclofenac with the aim of optimisation of its safe use
Location:	Montenegro
Name of the lead applicant	Agency for Medicines and Medical Devices of Montenegro (CALIMS)
Nationality of the lead applicant	Montenegro
Address of the lead applicant	Bul. Ivana Crnojevića 64A, 81000 Podgorica, Montenegro
Name of the partner	MG Soft d.o.o.
Nationality of the partner	Montenegro
Address of the lead applicant	Bul. Ivana Crnojevića 64A, 81000 Podgorica, Montenegro
Project start date:	16.03.2020.
Project duration:	24 months

Project Manager	Project Coordinator
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3. LEGAL ASPECTS

3.1. Grant Agreement

The Grant Agreement forms the legal basis for the implementation of the project. It consists of:

- Special conditions (this is the core contract);
- Annex I Grant application form (with Description of the Action);
- Annex II General conditions applicable to European Union-financed grant contracts for external actions;
- Annex III Budget for the action;
- Annex IV Procurement by grant beneficiaries in the context of European Union external actions;
- Annex V Request for payment for grant contract European Union external actions;
- Annex VI Final narrative report
- Annex VI Interim narrative report
- Annex IX Annex IX Transfer of ownership of assets

Although the core contract is signed between the Ministry of Finance - Directorate for Finance and Contracting of the EU Assistance Funds as Contracting authority and the Agency for Medicines and Medical Devices of Montenegro (CALIMS) as Coordinator of the project.

The project partner MG Soft d.o.o. have conferred powers of attorney for the purposes of the signature of the agreement to the Coordinator collectively referred to as 'Beneficiary' where a provision applies without distinction to the Coordinator and the co-beneficiary.

3.2. Partnership Agreement

Whereas the Grant Agreement is signed between the Contracting authority and Coordinator of the project, the Partnership Agreement on joint project implementation (PA) is signed between Agency for Medicines and Medical Devices of Montenegro (CALIMS) and MG Soft d.o.o.

It arranges in more detail the provisions of the Grant Agreement, such as but not limited to: financial issues, payments, management, decision making, conflict resolution, intellectual property rights and liability.

The Consortium Agreement must also be kept by the partners and must be shown in case of audits.

3.3. Amendments

During the project, circumstances may arise to call for a request to the Contracting Authority for an amendment of the Grant Agreement. Reasons may vary, but could be:

- Change of partner(s);
- Change of legal entity;
- Changes in the Budget;
- Changes in the DoA .

In case an amendment is needed the Project Manager shall submit such a request after an autonomous decision by all partners. After approval the Project Coordinator shall distribute the revised Grant Agreement to the partners, replacing former versions.

4. PROJECT EXECUTION

4.1. Main phases

The project *Monitoring the prescription of diclofenac with the aim of optimisation of its safe use* is articulated in the following six Work Packages (WP):

WP1 - Project management

WP2 - Creation of innovative IT solutions in the existing information system of CALIMS, which will enable obtaining of the key data on the prescription of diclofenac in PHC, starting from 2016 with a daily update, in order to monitor the effects of the project in the next stages

WP3 - Conducting of the Drug utilisation study – DUS of diclofenac, scientific analysis of obtained data on prescribing of diclofenac in PHC, preparational activities for publication of data in scientific journals

WP4 - Creation of innovative IT solution which will reduce diclofenac prescribing

WP5 - Scientific analysis and comparation of data on the prescription of diclofenac before and after, by innovative solutions imposed restrictions in prescribing of diclofenac, preparational activities for publication of these data in relevant scientific journals

WP6 - Raising awareness, dissemination and builing innovative and scientific capacity

4.2. Deliverables

Summary list of deliverables with expected delivery time is listed below:

(DEV) 1.1 - Consortium Meetings and Minutes - M3, M6, M9, M12, M15, M18, M21, M24

(DEV) 1.2 - Project Handbook – M2

(DEV) 1.3 - Reports on quality monitoring, assessment and control – M6, M12, M18, M24

(DEV) 2.1 - Report “Data warehouse model for prescribing medicine in PHC” M3

(DEV) 2.2 - Report “Business Intelligence tools for data analysis of prescribed medicines” -M4

(DEV) 2.3 - Reports on organized user trainings and workshops in CALIMS - M5

(DEV) 3.1 - Report “Analysis of obtained data on prescribing patterns of diclofenac in PHC” – M9

(DEV) 3.2 - Report “Assesment of compliance or deviation of diclofenac prescribing in PHC” – M10

(DEV) 3.3 - Report on scientific research and statistical analysis of data with aim of publishing – M12

(DEV) 4.1 - Report “Description of possibilities to setup rules and controls in PHC IS ” – M14

(DEV) 4.2 - Report “Definition of SOAP Web services for communication between PHC IS and CALIMS IS ”- M14

(DEV) 4.3 - User documentation on new functionalities in PHC IS and CALIMS IS.- M15

(DEV) 5.1 - Report “Analysis of obtained data on prescribing patterns of diclofenac in PHC, after introduction of IT measure to rationalise prescribing of diclofenac” –M21

(DEV) 5.2 - Report “Assesment of compliance or deviation of diclofenac prescribing in PHC with evidence based CALIMS and EMA recommendation",after introduction of IT measure to rationalise prescribing of diclofenac” –M22

(DEV) 5.3 - Report "The effectiveness of the introduced new risk minimization measure (by CALIMS and MG SOFT) on the prescription and consumption of diclofenac in the PHC(DEV) –M23

(DEV) 5.4 - Scientific research and statistical analysis of data with the aim of publishing in relevant scientific journals - M24

(DEV) 6.1 - Report “ Dissemination Strategy and Exploitation Plan” – M1, M6, M12, M18, M24

(DEV) 6.2 - Report on dissemination activities - M6, M12, M18, M24

(DEV) 6.3 - Report "Building scientific and innovative capacities in CALIMS and MG SOFT" - M12, M18, M24

4.3. Activity plan

In the following table, timeframe for action plan is presented as well as expected time for deliverables listed below the table.

Year 1													
	Half-year 1						Half-year 2						
Activity	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**Implementing body**
1.1. Overall management activities		Dev 1.2											leader: CALIMS, participant: MG SOFT
1.2. Project coordination meetings			Dev 1.1			Dev 1.1			Dev 1.1			Dev 1.1	leader: CALIMS, participant: MG SOFT
1.3. Quality monitoring, assessment and control						Dev 1.3						Dev 1.3	leader: CALIMS, participant: MG SOFT
2.1. Development of Data Warehouse model for prescription of medicines in PHC IS			Dev 2.1										MG SOFT
2.2. Implementation of Data Warehouse for prescription of medicines in PHC IS													MG SOFT
2.3. Implementation and installation of Business Intelligence tools in CALIMS IS				Dev 2.2									MG SOFT
2.4. User training for BI for CALIMS professionals					Dev 2.3								MG SOFT
3.1. Analysis of obtained data on prescribing patterns of diclofenac in PHC									Dev 3.1				CALIMS

3.2. Assessment of compliance or deviation of diclofenac prescribing in PHC with CALIMS and EMA recommendation of its safe use										Dev 3.2			CALIMS
3.3. Scientific research and statistical analysis of data with aim of publishing in relevant scientific journals												Dev 3.3	CALIMS
4.1. Definition of rules for messages and warnings in PHC.													MG SOFT
4.2. Development of SOAP Web service server on CALIMS IS side.													MG SOFT
4.3. Development of SOAP Web service client on PHC side.													MG SOFT
4.4. Upgrade of PHC IS for functionalities of medicine prescribing.													MG SOFT
4.5. Upgrade od CALIMS IS for setting up rules and monitoring of medicine prescribing.													MG SOFT
5.1. Scientific analysis of obtained data on prescribing patterns of diclofenac after imposing the restrictions of its use via information system (indications, administered dose, duration of therapy, medicines in concomotant use, comorbidities, contraindications, warnings and precautions)													CALIMS
5.2. Assesment of compliance or deviation of diclofenac prescribing in PHC, after introduction of IT tools to rationalise its prescribing													CALIMS

5.3 Assessment of the effectiveness of the introduced new risk minimization measure (by CALIMS and MG SOFT) on the prescription and consumption of diclofenac in the PHC, in terms of the rationalisation in the consumption of diclofenac in Montenegro.													CALIMS
5.4. Scientific research and statistical analysis of data with the aim of publishing in relevant scientific journals.													CALIMS
6.1. Dissemination Strategy and Exploitation Plan	Dev 6.1					Dev 6.1						Dev 6.1	leader: CALIMS, participant: MGSoft
6.2. Reports on dissemination activities (dissemmination of intermediate and final results)						Dev 6.2						Dev 6.2	leader: CALIMS, participant: MGSoft
6.3. Improvement of scientific and innovative capacity in CALIMS and MG SOFT												Dev 6.3	leader: CALIMS, participant: MGSoft

Year 2													
	Half-year 1					**Half-year 2**							
Activity	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**Implementing body**
1.1. Overall management activities													leader: CALIMS, participant: MG SOFT
1.2. Project coordination meetings			Dev 1.1			Dev 1.1			Dev 1.1			Dev 1.1	leader: CALIMS, participant: MG SOFT

1.3. Quality monitoring, assessment and control						Dev 1.3						Dev 1.3	leader: CALIMS, participant: MG SOFT
2.1. Development of Data Warehouse model for prescription of medicines in PHC IS													MG SOFT
2.2. Implementation of Data Warehouse for prescription of medicines in PHC IS													MG SOFT
2.3. Implementation and installation of Business Intelligence tools in CALIMS IS													MG SOFT
2.4. User training for BI for CALIMS professionals													MG SOFT
3.1. Analysis of obtained data on prescribing patterns of diclofenac in PHC (indications, administered dose, duration of therapy, medicines in concomitant use, comorbidities, contraindications, warnings and precautions)													CALIMS
3.2. Assessment of compliance or deviation of diclofenac prescribing in PHC with CALIMS and EMA recommendation of its safe use													CALIMS
3.3. Scientific research and statistical analysis of data with aim of publishing in relevant scientific journals													CALIMS
4.1. Definition of rules for messages and warnings in PHC.		Dev 4.1											MG SOFT
4.2. Development of SOAP Web service server on CALIMS IS side.		Dev 4.2											MG SOFT
4.3. Development of SOAP Web service client on PHC side.			Dev 4.3										MG SOFT
4.4. Upgrade of PHC IS for functionalities of medicine prescribing.			Dev 4.3										MG SOFT
4.5. Upgrade od CALIMS IS for setting up rules and monitoring of medicine prescribing.			Dev 4.3										MG SOFT

5.1. Scientific analysis of obtained data on prescribing patterns of diclofenac after imposing the restrictions of its use via information system									Dev 5.1				CALIMS
5.2. Assesment of compliance or deviation of diclofenac prescribing in PHC, after introduction of IT tools to rationalise its prescribing										Dev 5.2			CALIMS
5.3 Assessment of the effectiveness of the introduced new risk minimization measure (by CALIMS and MG SOFT) on the prescription and consumption of diclofenac in the PHC, in terms of the rationalisation in the consumption of diclofenac in Montenegro.											Dev 5.3		CALIMS
5.4. Scientific research and statistical analysis of data with the aim of publishing in relevant scientific journals												Dev 5.4	CALIMS
6.1. Dissemination Strategy and Exploitation Plan						Dev 6.1						Dev 6.1	leader: CALIMS, participant: MGSoft
6.2. Reports on dissemination activities (dissemmination of intermediate and final results)						Dev 6.2						Dev 6.2	leader: CALIMS, participant: MGSoft
6.3. Improvement of scientific and innovative capacity in CALIMS and MG SOFT												Dev 6.3	leader: CALIMS, participant: MGSoft

4.4. Reporting

Reporting about project activities between project partners will be obtained trough email communication and coordination meetings.

The reporting to Contracting Authority will be obtained according to the Activity plan on defined reporting templates.

4.5. Risk assessment

The Project Coordinator will overview the overall risk management of the project and make general risk assesment.

In case that a member of project identifies a risk for the project, he/she must inform the Project Coordinator in written. Identified Risk will be evaluated depending on the severity of consequences and chance of happening by the Project coordinator, Project Manager and leaders of the project organisational structure and Project Coordinator will make written document about it.

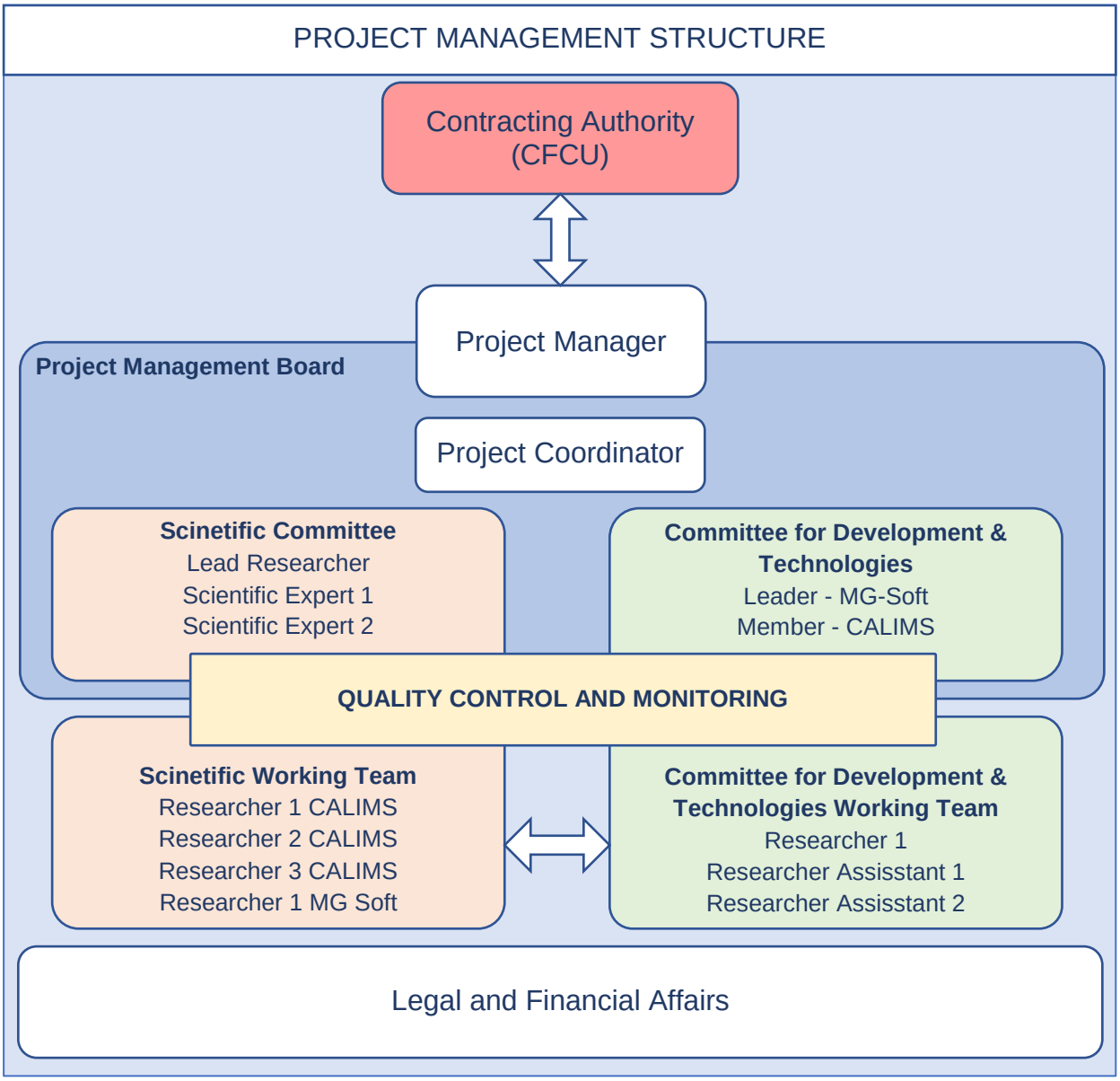
Risk assessment according to the COVID-19 pandemic is obligatory.

Reporting about risk assessment will be notified in coordination meetings between project partnes.

5. MANAGEMENT STRUCTURE

6.1. Project organizational strucure

The project organizational structure is represented in the following diagram:



The organisational (management) structure is consisted of:

- Project Manager (PM)
- Project Management board (PMB)
- Scientific Committee (SC)
- Committee for Developement & Technologies (CDT)
- Financial and Legal Affairs

The tasks of the management structure are:

- To ensure that the project activities take place within the established timeframe and budget,
- To monitor the progress of the project and to ensure the quality of the deliverables,
- To establish decision making procedure,
- To ensure that the project is developed in accordance with the rules defined by the call,
- To ensure coordination of activities, organization of work and communication (appropriate exchange of information.

Project Manager and The Project Management Board (PMB) led by Project Coordinator are responsible for achievement of all outcomes during project lifetime and continuous organizing and coordinating. CALIMS is also in charge for effective communication, reporting and accounting.

Both partners in the project (CALIMS and MG Soft) have full financial and technical responsibility for the project management.

6.2. Roles

5.2.1. Project Manager (PM)

Project Manager act as a liaison between Consortium partners and the Grant Providers. Project Manager is responsible for scientific and educational part of the project.

5.2.2. Project Management Board (PMB)

Project Management Board is one hierarchical level below the Project Manager. It consist of representatives from both Project Coordinator (CALIMS) and Project Partner (MG Soft) and if any problem occur Project Coordinator reports immediately to Project Manager for solving the problem.

Tasks of the PMB:

- manage all project activities,
- coordination between participants,
- financial supervision,
- drafting of reports, their revision, preparation and submission of final reports,
- monitoring and evaluation of the project results.

Project Management Board is led by Project Coordinator.

5.2.3. Scinetific Comitee (SC)

Scientific committee providing a high level of excellence in the scientific part of the project, its visibility and promotion to the health, scientific and wider community. Competences of the Scientific Committee are listed as follows:

- managing scientific, educational and promotional aspect of the project, in order to ensure that the appropriate working packages with the envisaged scientific/educational and promotional activities are implemented, in accordance with the deadlines and the planned budget.
- prepares a report from relevant scientific/educational/promotional working packages, in accordance with deadlines
- monitoring the progress of project activities from relevant scientific/educational and promotional working packages

Scientific Committee will engage the EMA employee, dr Viola Macolić Šarinić, who is an expert in pharmacovigilance, pharmacoepidemiology and scientific evaluation of documentation on safety and efficacy of medicines, with great experience in the field of rational pharmacotherapy and risk minimization from the use of medicines as well as experience in a large number of projects successfully implemented in EU Member States and beyond.

Scientific Committee will also engage a regular professor at the Medical School of the Military Medical Academy at the Ministry of Defense of Serbia, whose participation provides strong scientific support for project activities, strengthening CALIMS' scientific capacities and support for young CALIMS researchers. Prof. Silva Dobrić is also the head of the Institute for Scientific Information of the Military Medical Academy and editor-in-chief of the Military Medical Review, a significant scientific journal.

Mentioned scientists/experts who will support scientific and research activities of this project are on the CALIMS Expert List and are engaged in the procedures for assessing the documentation on quality, safety and efficacy of medicines in the procedure for issuance of marketing authorisations. Their names and contacts are available on the web portal CALIMS - www.calims.me.

Members of the Scientific Committee are 3 PhD students, young researchers from CALIMS and one employee with expertise in safety of medicines.

The Scientific Committee will also include representatives of the academic institutions, relevant HCPs, patients and their associations, representative of the HIF, in order to take their opinions and attitudes into account when making appropriate decisions and measures.

Scientific Committee is led by Lead Reasercher.

5.2.4. Committee for Developement & Technologies (CDT)

Committee for Developement & Technologies is led by representative of MG Soft an ensures high level of professional development and all technical and technological support for the project. The Committee for Developement & Technologies is led by representative of MG Soft and include also include representatives from CALIMS in order to achieve full coordination in development of new software functionalities.

5.2.5. Financial and Legal Affairs

Financial and Legal Affairs for project activities are led from representatives of CALIMS. There are managers for both, financial and legal affairs.

5.2.6. Members

Name	Function	Institution	email
Maja Stanković	Project Manager	CALIMS	maja.stankovic@calims.me
Project Management Board			
Denis Reković	Project Coordinator	CALIMS	denis.rekovic@calims.me
Radovan Sekulić	Member	MG Soft	radovan.sekulic@Mg-soft.co.me
Scientific Commitee			
Maja Stanković	Lead Reasercher	CALIMS	maja.stankovic@calims.me
Viola Macolić	Scientific Expert 1	-	-
Silva Dobrić	Scientific Expert 2	-	-
Committee for Development &Technologies			
Radovan Sekulić	Leader	MG Soft	radovan.sekulic@Mg-soft.co.me
Denis Reković	Member	CALIMS	denis.rekovic@calims.me
Scientific Committee Working Team			
Željka Bešović	Reasercher 1	CALIMS	zeljka.besovic@calims.me
Nemanja Turković	Reasercher 2	CALIMS	nemanja.turkovic@calims.me
Veselinka Vukićević	Reasercher 2	CALIMS	veselinka.vukicevi@calims.me
Nataša Đurović	Researcher1	MG Soft	natasa.djurovic@mg-soft.co.me
Committee for Development &Technologies Working Team			
Nataša Đurović	Researcher	MG Soft	natasa.djurovic@mg-soft.co.me
Nataša Živković	Researcher Assisstant 1	MG Soft	natasa.zivkovic@mg-soft.co.me
Mlađen	Researcher	MG Soft	mladjen.mladenovic@calims.me

Mladenović	Assisstant 2		
Financial and Legal Affairs			
Svetlana Raonić	Financial Manager	CALIMS	svetlana.raonic@calims.me
Vesna kostić	Legal Mamanger	CALIMS	vesna.kostic@calims.me

5.2.7. Quality and Control Monitoring

For assuring the quality of the project a project management handbook summarising all the required knowledge for the good management of the project (in terms of administrative forms, templates, financial aspects, communication procedures, deliverables schedules, reporting periods, contacts, etc…), ethical questions (conflicts of interest management) and conflicts resolution, will be defined when the project starts. Additionally, besides the external advisory peer review process, the project will have an internal peer-reviewing procedure to assure the quality of processes and results. Each deliverable will be peer-reviewed by some members of the consortium.

6.3. Project coordination

The Project is managed by Project Manager that acts as the intermediary between the project partners (CALIMS and MG Soft) and the exterlnal parties (Contracting Authority, Ministry of Science, consultant firms, etc.).

The coordination of the project is performed at three levels:

Scientific coordination

Maja Stanković is the scientific coordinator and she take care of the scientific development of the project. The main responsibility is to ensure that the main goals of the project are pursued and to verify the quality of all deliverables resulting from the project. She is also Project Manager.

Project coordination

Denis Reković is the project coordinator. He assists the scientific coordinator and the partners on financial, legal, administrative as well as on organizational matters.

The scientific coordinator and project coordinator work closely together to guarantee a smooth project communication internally (within the project) and externally.

6. COMMUNICATION

6.1. Internal communication

Internal communication is considered the communication within the consortium.

6.1.1. E-mail

Participants on the project are likely to receive numerous emails every day, therefore, a standard subject title is proposed. This helps to quickly recognise the project related emails.

Project related e-mails should include in the subject title: 'DIKLOFENAC' and WP number (if applicable) followed by a more specific description of the subject, deadline for feedback or reply, see below an example:

[Subject: DIKLOFENAK: Kick off meeting minutes, till May 11th 2020].

Furthermore it is required to copy the Project Manager and Project Coordinator in most important e-mail communications.

6.1.2. Internal network share as project repository

Internal network share was set up to act as repository for all working documents, minutes and reports. The address of the network share is:

\\dok\PUBLIC\Projekat - Propisivanje Diklofenaka

Every member of the CALIMS Project Team has access to the internal network share. Person in charge for general administering Internal network share (user rights, folders, etc.) is Project Coordinator.

Permission levels

There are different permission levels on this network share. Project Manager, Project Coordinator and Financial and Legal Manager can use the Internal network share to read/download/edit/ upload documents.

Other users can use this Internal nwteork share to read and download project documentation. In case they want to upload a final document, they can contact their Committee leader od the Project Coordinator.

6.2. External communication

External communication is considered towards parties outside the project partners, target groups of the project, stakeholders and the Contracting Authority.

Overall external communication objective is to raise awareness among defined target groups and final beneficiaries (scientific and IT communities, patients, HCPs, creators of health policy) on rational use of medicines and importance of synergy between science and innovation (IT solutions) for that purpose.

Specific communication objectives includes:

- promotion of intermediate and final project results to key target group and final beneficiaries with focus on HCPs in PHC as prescribers of diclofenac
- publishing of obtained results in relevant scientific journals after thorough scientific analysis of obtained data on diclofenac prescribing
- delivering of key messages (recommendations) on diclofenac rational use
- delivering of key messages (recommendations) on diclofenac rational usethrough IS that HCPs use in they daily work.

6.2.1. General Requirements

It is requested to indicate at all times that the project has received funding support from the European Union according to *Communication and Visibility in EU-financed external actions Manual* using the following:

(a) display the EU emblem (When displayed together with another logo, the EU emblem must have appropriate prominence.):

(b) include the following Disclaimer:

For publications in print or electronic format:

'This publication was produced with the financial support of the European Union. Its contents are the sole responsibility of <name of the author/partner> and do not necessarily reflect the views of the European Union';

For websites and social media accounts:

'This <website/account> was created and maintained with the financial support of the European Union. Its contents are the sole responsibility of <name of the author/partner> and do not necessarily reflect the views of the European Union'

For videos and other audio-visual material:

'This <video/film/programme/recording> was produced with the financial support of the European Union. Its contents are the sole responsibility of <name of the author/partner > and do not necessarily reflect the views of the European Union.'

(c) Include the project logo that could be find on the Internal network share once finished. It is recommended to always place the project logo on the front page of the document and the EU logo at the left side of the footer of the first page in the document.

6.2.2. E-mail

Default communication channel between project partners and external parities on the project is email communication. It is likely to receive numerous emails every day, therefore, a standard subject title is proposed. This helps to quickly recognise the project related emails.

Project related e-mails between Project partners and CFCU should include in the subject title: 'Monitoring the prescription of diclofenac with the aim of optimisation of its safe use - CFCU/MNE/128' followed by a more specific description of the subject, deadline for feedback or reply, see below an example:

[Subject: Monitoring the prescription of diclofenac with the aim of optimisation of its safe use - CFCU/MNE/128 - Pitanje u vezi sa Time Sheet].

6.2.3. Project web site

In accordance with the dissemination plan and addition to publishing information about EU-financed action dedicated, externally hosted website about the project will be established. The project website should be accessed directly or indirectly through the CALIMS (project coordinator) website.

Project web site will comply with the criteria for appropriate communication and visibility set out in *Communication and Visibility in EU-financed external actions Manual* and all visibility requirements will be implemented according to the Grant contract and Annex 2 of the Grant Contract. The EU emblem accompanied by text acknowledging the Union's support will be prominently featured. Project web site will be created to promote the project, its results and finally impact to expert (HCPs) and general audience (patients) as key target groups and to final beneficiaries as well.

All relevant information about the project (objectives, information, news, event announcements, public reports, analysis…) will be published on the project web site.

6.2.4. Specific project presentation

There are other different kinds of external communication shoul be obtained such as *Promotional materials* and *Project events and Publications.*

All these kinds of external communications will be obtained regarding the General requirements of external communication given on this document.

6.4. Document Templates

All public documentation needs to conform the document templates provided by the Project Coordinator. The document standard could be used for:

- Official EU reports (such as Interim, Final);
- Public documents by the consortium;
- Project deliverables (in a report format);
- any documents that are declared as public by project partners; and
- internal project documents.

All project templates can be found on Internal network share and on the Project Web site.

7. LIST OF ANNEXESS

- Grant Agreement with Special conditions;
- Annex I Grant application form (with Description of the Action);
- Annex II General conditions applicable to European Union - financed grant contracts for external actions;
- Annex III Budget for the action;
- Annex IV Procurement by grant beneficiaries in the context of European Union external actions;
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