



# REPORT ON QUALITY MONITORING, ASSESSMENT AND CONTROL DEV 1.3

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

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Authors:	Maja Stanković, Project Manager and Denis Reković, Project Coordinator
Institution:	CInMED
Email:	<a href="mailto:maja.stankovic@cinmed.me">maja.stankovic@cinmed.me</a> ; <a href="mailto:denis.rekovic@cinmed.me">denis.rekovic@cinmed.me</a>





## List of Abbreviations

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<b>C&amp;VP</b>	<b><i>Communication and Visibility Plan</i></b>
<b>EU</b>	<b><i>European Union</i></b>
<b>BI</b>	<b><i>Bussiness Inteligence</i></b>
<b>DW</b>	<b><i>Data Warehouse</i></b>
<b>PHC</b>	<b><i>Primary Health Care</i></b>
<b>IT</b>	<b><i>Information Technology</i></b>
<b>IIHS</b>	<b><i>Integral Information Healthcare System</i></b>
<b>HCP</b>	<b><i>Healthcare Professionals</i></b>
<b>HCIs</b>	<b><i>Healthcare Institutions</i></b>
<b>CInMED</b>	<b><i>Institute for Medicines and Medical Devices</i></b>
<b>MoH</b>	<b><i>Ministry of Health</i></b>
<b>HIF</b>	<b><i>Health Insurance Fund</i></b>
<b>DoA</b>	<b><i>Description of the Action</i></b>
<b>WP</b>	<b><i>Work Package</i></b>





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## 1. INTRODUCTION

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This report is an evidence-based snapshot of the project's status at the time of the review. It reflects the views based on information evaluated over the review period.

This project refers to monitoring the prescription of diclofenac and optimization of its safe use in PHC institutions, through innovative Information Technology (IT) solutions, with a scientific analysis, evaluation and publication of obtained data. By upgrading existing IT solutions into an Integral Information Healthcare System (IIHS) and creating new ones, scientific research in the field of rational use of medicines will be strengthened and thus contribute to improvement of health of people and society as a whole. In order to achieve defined goals and objectives, the activities covered by this project include activities related to implementation but also activities related to continuous support, in terms of project management and dissemination of project results to target groups and final beneficiaries. The Scientific community will also be involved through preparation of scientific articles for publishing in relevant scientific journals. For this reason, two work packages (WP) exclusively refers to overall project management activities and dissemination activities, while the remaining work packages refer to the implementation of different types of activities.

These implementation activities encompasses scientific analysis and comparison of data on the prescription of diclofenac before and after, by innovative IT solutions imposed restrictions in its use. These activities will be performing with the aim to achieve the expected results and finally the expected impact of the project.

**The expected results** of the project:

**Result 1.** Engagement of young and experienced researchers to scientific analyze the observed problem of nonrational use of diclofenac, which will improve scientific potential and visibility of CInMED in the domain of rational use of medicines.

**Result 2.** Development of innovative IT solutions, thanks to which the prescribing and use of diclofenac is going to be optimized.

**Result 3.** Improvement and better integration of Information System (IS) of CInMED and PHC.

**Result 4.** Optimising the prescription and consumption of diclofenac in PHC institutions in Montenegro.

**Result 5.** Harmonizing the prescription of diclofenac in PHC institutions with CInMED evidence based recommendations.

**Impact** - The strengthening of synergy between science and innovation, stimulating research and development of science, cooperation between the public and the private sector in improvement of human health and finally improvement of visibility and importance of CInMED in Montenegrin health and scientific community.





## 2. QUALITY CONTROL AND MONITORING OF PROJECT MANAGEMENT

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The project management structure was established at the project's Kick-off meeting regarding project management structure defined in Annex I of the contract to ensure effectiveness, decisiveness, flexibility and quality of work. It involves the Coordinator of the project (CInMED) and Project partner (MG-Soft) project teams.

At the Kick-off meeting was established, where all project partners have representative members and where director and executive director has been present.

Project management team is formed from:

- ✓ Project management board (Director of CInMED and Executive director of MG-Soft)
- ✓ Project Manager (CInMED),
- ✓ Project Coordinator (CInMED)
- ✓ Scientific Comitee
- ✓ Committee For Development & Technologies
- ✓ Scientific Working Team
- ✓ Committee For Developments Technologies Working Team

Regarding all project activities and emphasizing the COVID19 pandemic risks, the Project Manager has been reviewed all activities and decide on any necessary contingency measures in reorganisation tasks and resources – as usual with a strong focus on the project impact.

The project management is transparent and flexible but also strict enough to ensure the implementation of the project activities in order to achieve the project's objectives. Project coordinator is responsible for administrative part of the project and preparation of particular reporting on activities.

Each partner is equally and independently responsible for assigned activities, money use and reporting. All team leaders have the responsibility to the Project manager and Project coordinator.

All coordination and work between Coordinator and Project partner were communicated by mail or on meetings (live or online).

Due to the COVID19 pandemic, lot of meetings and workshops were realized over online video-conferencing systems ZOOM (CInMED has pro license) or Skype (free use) and the duration of the project has been extended for eight months to have enough time to collect data from PHC, make appropriate analisys and prepare scientific articles for publishing.





### 3. QUALITY CONTROL AND MONITORING OF PROJECT DELIVERABLES

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The present chapter presents the expectations of the project with reference to the deliverables and activities as well as the expectations relevant to the project management.

The deliverables may be classified into tangible deliverables such as reports, publications, printed and electronically available promotional material, media articles as well as intangible deliverables in the form of organized events (workshops, coordination meetings, etc.), developed and launched project web site etc.

A common quality expectation for all deliverables is their relevance to reach the overall objective and the specific objectives, with a further focus on their development in an efficient and effective manner. Timely delivery following the project workplan as identified in the Activity plan.

#### 2.1. Quality of document based deliverables

A consistent and common format for all document based deliverables (word document, power point presentations) is to be followed by all partners using templates provided within this Plan:

- ✓ Project document template
- ✓ Project Minutes template
- ✓ Event attendance list - template

All templates are adopted in order to ensure a common appearance of deliverables as well as to ensure that a minimum amount of information will appear consistently in all documents produced by the project.

This is not relevant to deliverables that by their nature need to have a different format (i.e. project brochures, newsletters).

In the review period the documented deliverables with expected delivery times 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

(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) 2.1 - 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 CInMED - 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 CInMED IS "- M14
- (DEV) 4.3 - User documentation on new functionalities in PHC IS and CInMED 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 CInMED 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 CInMED 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 CInMED and MG SOFT" - M12, M18, M24

All document based deliverables has been made in defined form (templates) and on time regarding bearing in mind the permitted delay of some activities and extension of the project and has been verified by the Project manager.

## **2.2. Quality of development of Data Warehouse model for prescription of medicines in PHC IS**

The Data Warehouse model for prescription of medicines in PHC IS is developed with approval of Health Insurance Fund, where is the centre of the Integral Health Information System as the source of data.

Datawarehouse is developed by MG-Soft in cooperation with CInMED Scientific comitee leader and Scientific working team members that were made tests and verification of all functionlities of developed BI software.







After the development phase, Scientific team has been working on BI software and there was no problems in functioning.

### 2.3. Quality of the project websites and other electronic media

The project envisages setting up the public part of Project (web site of the project) and Intranet part – CInMED file share platform as intranet tool for project communication and project management within project members of CInMED.

The file share in CInMED has been accessible by all project members in CInMED with the purpose to keep all project documents and deliverables on one place. This has been the single point of reference for the project documentation in CInMED.

The web site as representation tool is continuously updated and are intended to effectively communicate activities and the results of the project with public.

Moreover, both partners has promoted Project on their websites by providing short description of the project, logo, project events and link to Project website.

The web site is implemented with high performance, good functionality and stability, emphasizing the maximum reach and awareness of the target audience, and there was no downtime in services during all project period.

### 2.4. Quality of scientific and promotional materials

As “User training for BI for CInMED professionals (DEV 2.3) has been realized over online video-conference and planned Workshop for CInMED target groups has been delayed due to COVID19 pandemic there was no publishing promo materials for this event.

On June 24 Project team CInMED has been held the presentation of project to the representatives of Ministry of Health (MoH, one representative) and Health Insurance Fund (HIF, four representatives). Participants were introduced to the project from the aspect of organization, resources and the team that implements it as the project's basic assumptions and project goals. It was also pointed out the role of MoH and HIF in the further implementation of the project relates to the acceptance of the recommendations of the research team and the implementation of these recommendations in primary health care (PHC) information system trough messages/warnings to physicians that will appear when prescribing Diclofenac. Representatives of both institutions expressed respect for this project and the scientific analyzes that were performed, as well as the approach aimed at streamlining the prescribing of diclofenac by sending messages / warnings through the information system during prescribing diclofenac.

They also expressed readiness for future support in the implementation of messages / warnings to be created.





After development of Data Warehouse model and BI software for prescription of medicines in PHC information system, Scientific team has been working on BI software and create the set of messages/warnings that should be implemented in information system that will appear when prescribing Diclofenac, as measure for rationalisation of prescribing diclofenac.

During september 2021, the CInMED project team has been prepared the brochure (A5, 16 page) and flyer (A4, divided on three parts) for workshop that should be held to healthcare professionals in PHC regarding the project and messages/warnings that should be implemented in information system that will appear when prescribing Diclofenac. Both, brochure and flyer, has been approved from CFCU regarding visibility elements and both has been published in amount of 100 pieces and distributed to PHC centers as the second workshop has been organized on-line due to pandemic.



*Brochure and Flyer, September 2021*





In October 2022, the CInMED project team has been prepared the (A5, 16 page) and flyer (A4, divided on three parts) for workshop that has been held to healthcare professionals in PHC regarding the results of the project regarding the messages/warnings implemented in information system that appear when prescribing Diclofenac. Both, brochure and flyer, has been published in amount of 100 pieces and distributed to PHC centers as the second workshop has been organized on-line due to pandemic.



*Brochure and Flyer, October 2022*

All the brochures and flyers were printed on high quality paper, and sent to PHC professionals bearing in mind that the two workshops for PHC professionals were held online due to pandemic.

## 2.5. Quality of dissamination and visibility

Apart from activities visible on project web site that are regularly performed (published) during the project has been made dissimulation and visibility activity - presentation of Project goals on TV Vijesti. All relevant information about the project are published on the project web site and reported in *Report on Dissemination Activities (DEV 6.2)* in more details.

All visibility activities are performed in coordination with Ministry of Science and both, brochure and flyer prepared for workshop that has been held to healthcare professionals in PHC, has been approved from CFCU regarding visibility elements.

## 2.6. Quality of implemented set of measures (messagess/warnings) in Primary Health Care Informatin System

The messagess/warnings were designed and implemented in such a way that they didn't make any negative affect in PHC information system and doctors work at all.





All implemented set of measures (messages/warnings) in Primary Health Care Information System were very good accepted from PHC professionals and they see it as the help in their ordinary work when prescribe Diclofenac.

## 2.7. Quality of prepared scientific articles

This project has strong scientific background. All data extracted from PHC IS are scientifically analysed with ultimate goal to publish two articles in scientific journals which are on SCI list.

One article is in final phase of reviewing by scientific article reviewers. After reviewing it is going to be published.

The other scientific article is prepared, at the moment in the phase of internal review before its submission to other scientific journal on SCI list in field of biomedicine.

Both articles are prepared according to the procedures of scientific journals and should be reviewed by scientific reviewers.

## 4. CONFLICT RESOLUTION

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There was no major conflicts between Coordinator of the project and Project partner during the project realisation.

Small conflicts and disagreements were solved at the lowest level with no need for mediation of Project Coordinator or higher instances.

All communication with CFCU and Ministry of Education, Science, Culture and Sports is fast, effective and without any problems.

Implementation of the messages/warnings that appear when prescribing Diclofenac has been implemented in Primary Health Care Information System (PHCIS) has been realized in cooperation of CInMED, MG-Soft and Health Insurance Fund that govern the PHCIS, and has been approved by Ministry of Health as significant change in PHC professionals work through IS.

All actions related to the notification of Primary Health Centers as well as individual doctors about the implemented messages/warnings in IS that will appear when prescribing Diclofenac were taken over by the Health Insurance Fund, both through e-mail communication to the Primary Healthcare Centers and by sending the notification's through the notification system that was developed in the primary health care information directly to the doctors. There was no problems in implementation and usage of implemented messages/warnings in IS by the PHC professionals.

All the activities were performed according to the Project handbook.

