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CYLCOMED

Cyber-security toolbox
for connected medical devices

D7.1 Dissemination, Communication, Standardisation and Exploitation Strategy and Plan

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Abstract	This deliverable presents the comprehensive strategy and plan for dissemination, communication, standardization, and exploitation within the CYLCOMED project. The deliverable also emphasizes the project's engagement in standardization activities and outlines the project's exploitation objectives, including the development of an exploitation strategy, market analyses, and identification of key exploitable results.
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Nature of the deliverable:	R
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PU	<i>Public, fully open, e.g. web</i>	x
SEN	<i>Sensitive, limited under the conditions of the Grant Agreement</i>	
Classified R-UE/ EU-R	<i>EU RESTRICTED under the Commission Decision No2015/ 444</i>	
Classified C-UE/ EU-C	<i>EU CONFIDENTIAL under the Commission Decision No2015/ 444</i>	
Classified S-UE/ EU-S	<i>EU SECRET under the Commission Decision No2015/ 444</i>	

- * *R: Document, report (excluding the periodic and final reports)*
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.
DATA: Data sets, microdata, etc
DMP: Data management plan
ETHICS: Deliverables related to ethics issues.
SECURITY: Deliverables related to security issues
OTHER: Software, technical diagram, algorithms, models, etc.



Executive summary

The deliverable focuses on the project's objectives and strategies related to disseminating project outcomes, communicating project progress, engaging in standardisation activities, and developing an exploitation plan for the project results.

The deliverable highlights the comprehensive dissemination and communication activities that will be undertaken by the CYLCOMED project to maximize the impact and reach of its cybersecurity framework for Connected Medical Devices. Through a strategic approach, the project aims to successfully disseminate project outcomes, research findings, and technological advancements to a wide range of stakeholders, including healthcare professionals, regulatory bodies, industry experts, and the general public.

The dissemination strategy encompassed various channels, such as scientific publications, conferences, workshops, and webinars, ensuring the widespread dissemination of knowledge and promoting dialogue within the medical and cybersecurity communities. Additionally, targeted dissemination efforts were tailored to specific audiences, facilitating the adoption of the project's outcomes by relevant stakeholders.

In addition, the project outlines a standardisation mission that involves studying specific standards, assessing their development status, and exploring opportunities for improvement based on the project's results. Partners' involvement with Standards Development Organizations (SDOs) is monitored, and training sessions on relevant standards are conducted to increase awareness and foster active participation.

The deliverable presents also a consortium exploitation plan that involves identifying exploitable results, conducting market analysis, and formulating individual exploitation strategies for each partner. The plan is intended to facilitate the successful adoption and exploitation of the project results, and it will be regularly reviewed and updated throughout the project.

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Abbreviations

ANSI	American National Standards Institute
AI	Artificial Intelligence
CAL	Cybersecurity Assurance Level
CEN	Comité Européen de Normalisation. <i>English:</i> European Committee for Standardization
CMD	Connected Medical Device
CPS	Cyber-Physical Systems
CS	CyberSecurity
D	Deliverable
GDPR	General Data Protection Regulation
FDA	Food and Drug Administration
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
IVDR	In Vitro Diagnostic Medical Devices Regulation
KPI	Key Performance Indicator
MDCG	Medical Device Coordination Group
MDD	Medical Devices Directive
MDR	Medical Device Regulation
NIS	Network and Information Systems
RAMS	Reliability, Availability, Maintainability, Safety
RMI	Repair and Maintenance Information
RoSPAV	Report on standardization prospective for automated vehicles
SAMD	Software as a Medical Device
SCP	Safety, Cybersecurity and Privacy
SDO	Standards Development Organization
SME	Small and Medium Enterprises
TAF	Target Attack Feasibility
TC	Technical Committees
TF	Task Force
UL	Underwriters Laboratories



V&V

Verification and Validation



1 INTRODUCTION

This deliverable presents the comprehensive strategy and plan for dissemination, communication, standardization, and exploitation within the CYLCOMED project. As cybersecurity threats continue to pose significant risks to Connected Medical Devices (CMDs), the CYLCOMED project aims to address these challenges by developing advanced methods and tools to enhance the security of CMDs. However, ensuring the success and impact of such a project goes beyond technical advancements alone. Effective dissemination and communication of project findings, active involvement in standardization efforts, and a well-defined exploitation strategy are crucial elements for driving adoption, collaboration, and long-term sustainability.

This deliverable outlines the key activities, objectives, and approaches undertaken by the CYLCOMED consortium in disseminating project outcomes, engaging in standardization initiatives, and planning for the exploitation of results. By focusing on these critical aspects, the CYLCOMED project aims to maximize its impact and contribute to the advancement of cybersecurity in the realm of Connected Medical Devices.

1.1 Structure of the document

This document serves as a comprehensive overview of Dissemination, Communication, Standardisation and Exploitation Strategy and Plan. The deliverable is structured as follows:

1. Introduction: This section provides an overview of the document, including its purpose and structure.
2. Section 2 “Communication and Dissemination Strategy and Plan”. This section outlines CYLCOMED’s communication and dissemination strategy and plan. It covers the mission, objectives, target audience, phases, engagement of the Advisory Board, tools and measures, online and offline channels, synergies and interaction with external initiatives, and impact assessment.
3. Section 3 “Standardization Strategy and Plan”. This section focuses on standards and the way that specific methods and tools developed by partners must comply with a specific standard. Therefore, in task 7.3, we intend to identify those standards that are more significant in the first place. This deliverable will present a preliminary plan to study in more depth the specific standards, learn the current development status of the standards and discuss possibilities of improvements. Through identification of specific standardization groups that could be approached and influenced by the project partners, proposals of improvements will be shared based on the results generated by the project partners in the remaining years of the project.
4. Section 4: “Exploitation strategy and plan”. This section aims to create a business and exploitation plan that will explore the potential for the development and exploitation of the methods implemented after the achievement of the Cylcomed project. All partners are involved in the exploitation activity by evaluating the potential use, marketability and the applicability of the key concepts and ideas for the evolution of the tools, methods or use cases.
5. Conclusions: This section provides a summary of the document and highlights key takeaways.

2 COMMUNICATION AND DISSEMINATION STRATEGY AND PLAN

2.1 CYLCOMED mission

The CYLCOMED (Cybersecurity Framework for Connected Medical Devices) project aims to develop a comprehensive, user-friendly, and innovative cybersecurity framework for connected medical devices (CMD) to ensure patient safety, data privacy, and overall resilience against cyber threats. By bridging the gap between healthcare and cybersecurity domains, CYLCOMED strives to establish itself as a leading project in securing medical devices and promoting collaboration among various stakeholders.

The mission of CYLCOMED is to:

- Develop a state-of-the-art cybersecurity framework tailored for connected medical devices that addresses the specific needs of healthcare providers, patients, and industry players in securing sensitive data, ensuring patient safety, and enhancing the overall resilience of CMD against cyber threats.
- Foster collaboration between stakeholders from the healthcare and cybersecurity sectors to drive innovation, share knowledge, and promote the adoption of the developed cybersecurity framework.
- Raise awareness about the importance of cybersecurity in the context of connected medical devices and engage a critical mass of stakeholders to ensure that the project's results are effectively showcased and implemented.
- Contribute to relevant scientific domains, standardization efforts, and policy discussions to ensure the widespread adoption and sustainability of the developed cybersecurity framework.

2.2 Grounding CYLCOMED communication and dissemination strategy and plan

The CYLCOMED communication and dissemination strategy and plan are designed to maximize the project's impact by ensuring that its results reach a broad audience of stakeholders, from industry professionals to policymakers and the general public. The following key principles ground the strategy and plan, providing a solid foundation for effective communication, dissemination, and engagement.

1. Identifying target audiences: A crucial element of the strategy is to identify and segment the target audiences, including end-users, industry professionals, researchers, policymakers, and the general public. This will ensure that messages are tailored to each group's needs and interests, improving the effectiveness of communication and dissemination efforts.
2. Clear and consistent messaging: The CYLCOMED project will establish a strong, cohesive identity and messaging framework that communicates its objectives, results, and benefits in a clear and consistent manner. This will help to increase visibility, awareness, and understanding of the project across all target audiences.
3. Utilizing diverse communication channels: The strategy will leverage a variety of communication channels and formats, such as social media, newsletters, websites, press releases, videos, and events, to reach a wider audience and engage with stakeholders in different ways.

4. Collaboration and synergies: CYLCOMED will actively seek to establish partnerships and collaborations with relevant initiatives, research projects, and organizations, both at the national and European levels. This will help to increase the project's visibility, create new opportunities for knowledge sharing, and strengthen the impact of its results.
5. Monitoring and evaluation: The communication and dissemination efforts will be regularly monitored and evaluated to assess their effectiveness and adjust the strategy as needed. Key performance indicators (KPIs) will be defined to measure the success of various activities and ensure continuous improvement.
6. Aligning with project milestones: The communication and dissemination activities will be closely aligned with the project's milestones and progress. This will ensure that the latest results, updates, and developments are effectively communicated to the relevant stakeholders in a timely manner.

By grounding the CYLCOMED communication and dissemination strategy and plan in these principles, the project aims to maximize its impact, create strong engagement with stakeholders, and ultimately contribute to the successful uptake and implementation of the cybersecurity framework designed for health solutions.

2.3 Dissemination and communication objectives

CYLCOMED aims to establish a comprehensive cybersecurity framework for connected medical devices that promotes a safer, more innovative, and resilient healthcare industry. To maximize the impact of the project's work, the CYLCOMED consortium will develop and execute a well-structured impact creation strategy, focusing on dedicated dissemination, communication, and stakeholder engagement initiatives. The following dissemination objectives are set:

1. Ensure broad visibility and raise awareness about CYLCOMED by disseminating project results and establishing a recognizable identity that supports promotional and marketing efforts.
2. Reach, stimulate, and engage a critical mass of relevant stakeholders, ensuring the project's results are effectively showcased, leading to validation and further adoption of the developed cybersecurity framework for connected medical devices.
3. Facilitate exploitation of the project's outcomes and promote the development of innovative solutions based on CYLCOMED technologies and concepts.
4. Support key player engagement strategies in the project activities while promoting great visibility of the project demonstrators and lessons learned. This will lead to the creation of new business models and the transfer of project outcomes to various application domains within the value chain.
5. Foster impactful contributions to relevant scientific domains and standardization bodies, as appropriate and relevant to planned exploitation plans and the project's outcomes.
6. Establish liaisons and ensure close collaboration with relevant initiatives in the industry and R&I domains, targeting projects launched as a result of Horizon 2020 LEIT ICT, other similar initiatives, and projects funded in relevant calls.

2.4 CYLCOMED target audience

The success of the CYLCOMED project relies on effectively engaging a diverse range of stakeholders. These stakeholders can benefit from the project's outcomes and contribute to its overall impact. This section provides an overview of the target stakeholders, the benefits of reaching them, key messages for each group, channels to reach them, and measures for engagement.

Table 1: CYLCOMED target audience, rationale, impact and communication channels

Target audience	Rationale	Expected impact	Communication and dissemination channels
Scientific Community	Promote research collaboration and foster scientific advancements	Enhanced knowledge exchange, collaborative research efforts	Conferences, workshops, publications, social media, newsletters
Healthcare Industry	Adoption of CYLCOMED framework, improved patient care	Wider implementation of the cybersecurity framework, increased industry trust	Industry events, trade shows, webinars, website, social media, newsletters
Cybersecurity Professionals	Opportunity for collaboration, knowledge exchange, and business growth	Development of innovative cybersecurity solutions for healthcare	Networking events, online forums, workshops, social media, newsletters, flyers
Medical Device Manufacturers	Improved cybersecurity for medical devices, market growth	Integration of robust cybersecurity measures, competitive advantage	Exhibitions, demos, training sessions, social media, website, newsletters
Healthcare Providers	Enhanced security and trust in medical devices	Better patient care through secure and reliable medical devices	Workshops, showcases, targeted publications, website, social media, newsletters
Patients and Caregivers	Increased awareness and trust in medical device security	Empowered patients and caregivers, informed decision-making	Social media, website, flyers, newsletters, targeted events

Key messages for each target group:

Scientific Community:

1. Collaborate on ground-breaking research and innovation in cybersecurity for healthcare.

2. Share and gain knowledge on the latest advancements in cybersecurity for connected medical devices.
3. Contribute to the development of a secure and reliable healthcare system through interdisciplinary research and collaboration.

Healthcare Industry:

1. Implement the CYLCOMED framework to ensure comprehensive cybersecurity for connected medical devices.
2. Improve patient care and trust by adopting robust security measures for medical devices.
3. Stay ahead in the competitive healthcare market by offering secure and reliable health solutions.

Cybersecurity Professionals:

1. Engage with industry leaders to develop innovative cybersecurity solutions for the healthcare sector.
2. Expand your knowledge and expertise by collaborating with experts in medical device cybersecurity.
3. Enhance the security and resilience of healthcare systems through cutting-edge cybersecurity practices.

Medical Device Manufacturers:

1. Integrate the CYLCOMED framework to strengthen the security of your medical devices.
2. Gain a competitive edge in the market by offering secure and reliable healthcare products.
3. Collaborate with industry stakeholders to ensure the highest standards of cybersecurity for your devices.

Healthcare Providers:

1. Trust and adopt medical devices secured by the CYLCOMED framework for improved patient care.
2. Stay informed on the latest cybersecurity practices for connected medical devices.
3. Participate in workshops and training sessions to enhance your knowledge of medical device security.

Patients and caregivers:

1. Learn about the importance of cybersecurity for connected medical devices and its impact on patient care.
2. Gain confidence in the security and reliability of medical devices secured by the CYLCOMED framework.
3. Stay informed about the latest advancements in medical device security to make better healthcare decisions.

2.5 Communication phases

CYLCOMED activities will encompass both offline and online communications, maintaining a strong digital presence, actively participating in and organizing events, engaging with other research and innovation projects within the domain, and establishing connections with relevant stakeholders and other EU research and innovation initiatives. Although the specific activities and their timeline will be further refined during the initial months of the project, the core structure of the proposed plan is organized into three stages.

- Phase 1 - Awareness creation and communication foundation (M01-M12):** This phase involves designing the communication strategy and plan, which includes refining target groups, selecting appropriate tools, and initiating community-building activities to inform all relevant stakeholders about CYLCOMED's scope and objectives. Key deliverables for this phase include the creation of the CYLCOMED website, the Communication and Dissemination Strategy and Plan, a dedicated calendar of events, a project introduction flyer, a slide-based project presentation, and the establishment of dedicated social media channels. Additionally, the consortium will participate in at least one conference or event presenting the CYLCOMED concept and circulate two editions of the e-newsletter.

Table 2: Communication activities identified for Phase 1

Activity	Description
CYLCOMED website	A website containing project information, updates, and resources
Social media channels	Dedicated channels on platforms like Twitter and LinkedIn to share updates and engage followers
E-Newsletter	A biannual newsletter to share project updates and news with subscribers
Calendar of events	A calendar outlining key project events and milestones
Project introduction flyer	A flyer summarizing the project's scope and objectives for distribution at events and conferences
Slide-based presentation	A presentation providing an overview of the project for use at conferences and events
Conference participation	Attending and presenting at industry conferences and events to showcase the project

These activities will help build awareness and establish a strong communication foundation for the CYLCOMED project during the first phase.

- Phase 2 - Dissemination and Stakeholder Engagement (M13-M24):** Proactively connect with target stakeholders, spark interest in CYLCOMED's activities and results, and establish a robust foundation for planned dissemination efforts. This phase also includes supporting the project's promotion, showcasing its activities, organizing and attending events, and highlighting project use cases. Furthermore, it aims to strengthen

collaboration with other H2020 or HE initiatives. Key activities in this phase include preparing slide-based presentations of initial project results, creating motion graphic videos, animating social media channels, publishing news items on the project website and newsletters, organizing and participating in selected events, hosting the first dedicated training workshop, producing scientific publications, and ensuring open access to the project's key results. Additionally, this phase involves co-organizing at least one event with other H2020 or HE initiatives and actively participating in other networking and joint activities, which may be facilitated by the European Commission (adequate travel budget has been allocated for beneficiaries in this regard).

Table 3: Communication activities identified for Phase 2

Activity Type	Description
Social media	Regularly update and engage with followers on platforms such as Twitter, LinkedIn, and Facebook, sharing project updates, news, and relevant content.
Newsletters	Periodically send out e-newsletters to subscribers, informing them about project progress, events, publications, and other relevant information.
Website	Maintain and update the project website with news, events, publications, and other important information related to the project.
Flyers and brochures	Design and distribute project flyers and brochures at events, conferences, and workshops to provide an overview of the project and its objectives.
Presentations	Prepare and deliver presentations at conferences, workshops, and other events to showcase the project's progress, results, and use cases.
Motion graphic videos	Create visually engaging motion graphic videos to explain the project's objectives, use cases, and results, for dissemination through social media channels and the project website.
Training workshops	Organize and host training workshops for stakeholders, focusing on the project's outcomes, technologies, and methodologies.
Scientific publications	Prepare and submit scientific publications to relevant journals and conferences, ensuring open access to the project's key results.
Networking events	Participate in and co-organize networking events with other H2020 or HE initiatives to foster collaboration, knowledge exchange, and joint activities.

- Phase 3 - Global outreach and sustainable impact (M24-M36):** Actively engage with and support the adoption and implementation of the concepts, technologies, and tools provided by CYLCOMED through targeted promotional activities, showcasing use cases, publishing additional scientific papers, creating and distributing promotional

materials, and ensuring open access to project results via the project website and open platforms. Participate in selected events, exhibitions, workshops, and exploitation activities while extending connections with relevant initiatives. As technologies develop and trials progress throughout the project's lifespan, standardization efforts will likely intensify. Organize a second training workshop for hospital staff and a workshop for developers, participate in exhibitions, and establish liaisons with related initiatives. Prepare promotional materials in various formats, publish research findings, and enhance synergies with relevant research and innovation projects and initiatives. Share news items on the website and social media, including papers, technical reports, additional e-newsletter editions, interviews, video clips, and event participation. Engage in CYLCOMED-based conferences, workshops, and tutorials, and contribute articles related to CYLCOMED results at high-profile conferences and in magazines. Organize a second training workshop and a workshop for developers.

Table 4: Communication activities identified for Phase 3

Activity Type	Description
Scientific papers	Publishing scientific papers related to the project's outcomes and technologies
Promo materials	Development and distribution of promotional materials to showcase CYLCOMED's achievements
Open Access results publication	Making project results openly accessible via the project website and open platforms
Events & exhibitions	Participation in selected events, exhibitions, workshops, and exploitation activities
Liaisons	Extending liaisons with relevant initiatives and projects
Special campaigns	Launching special campaigns to promote key project results
Training workshops	Organization of the second training workshop for hospital staff and a workshop for developers
News Items	Publishing news items on the website and social media, including papers, technical reports, interviews, and video clips
Conferences & workshops	Participation in CYLCOMED-based conferences, workshops, and tutorials
Magazine articles	Publishing articles related to CYLCOMED technologies and experiences in relevant magazines

2.6 Engagement of CYLCOMED Advisory Board

The CYLCOMED Advisory Board (AB) is composed of highly-regarded experts who provide effective means to optimize and fine-tune the project development. The board's collective experience and knowledge will be invaluable in guiding the CYLCOMED project towards success.

The AB consists of four experts:

- Antonio Kung, Co-founder of Trialog
- Alessia Moltani, CEO of Comftech S.r.l
- Stefano Finazzi, Researcher at the Laboratory of Clinical Data Science, Farmacological R. I. Mario Negri
- Sebastien Ziegler, Director at Europrivacy International Board of Experts in Data Protection

As part of the Communication and Dissemination Strategy and Plan, we intend to engage the AB members by producing interviews that will be featured on the CYLCOMED website and promoted on social media, covering topics related to the project.

Furthermore, the AB members have been invited to submit a brief biography and photograph for presentation on the CYLCOMED website. By showcasing their expertise and contributions, we aim to highlight the project's credibility and commitment to excellence.

2.7 Communication and dissemination tools and measures

2.7.1 Project's brand identity

As an EC-funded Research and Innovation project, it is crucial for CYLCOMED to establish a clear project brand identity to make a significant impact with the dissemination of its work and achievements.

A brand identity ensures consistent appearance across all outlets (electronic and printed visual media) and shapes the perception of those who come into contact with the brand. The recognition and perception of a brand are highly influenced by its visual presentation. A project's visual identity is the overall look of its communications, achieved by consistently using particular visual elements to create distinction, such as specific fonts, colors, and graphic elements.

The visual identity and guidelines for CYLCOMED have been finalized since the early stage of the project to secure a strong and unique brand. This identity will be incorporated into all promotional and dissemination materials produced during the project and will be used by all project partners in their communication activities.

The CYLCOMED logo is built with a graphic element on top and the project name at the bottom. The illustration is an abstraction of a medical symbol combined with technology elements, representing the project's focus on medical and technological advancements. The font of the project's name is modern, stable, highly readable (even at small sizes), and its slightly rounded aspect makes it stand out, creating a sense of innovation and trust, which are important aspects of the project.



Figure 1: CYLCOMED logo

The main logo is also provided in the variations depicted here below, to allow readability over dark backgrounds or for black and white printing purposes.

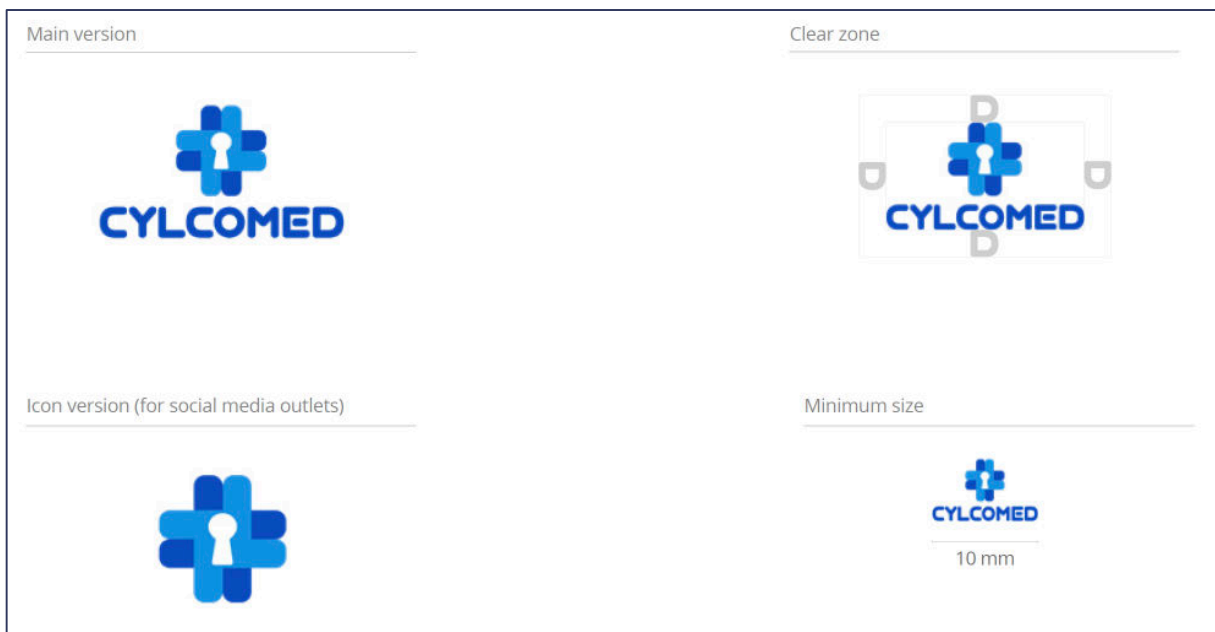


Figure 2: CYLCOMED logo variations

The guidelines of the brand identity are composed of visual elements such as the fonts, colour palette and templates for documents and presentations. The main palette of the corporate colours is composed of two colours based on the logo colour scheme plus a third complementary colour, very bright to highlight elements. Two more complementary greyscale colours complete the full CYLCOMED colour palette.

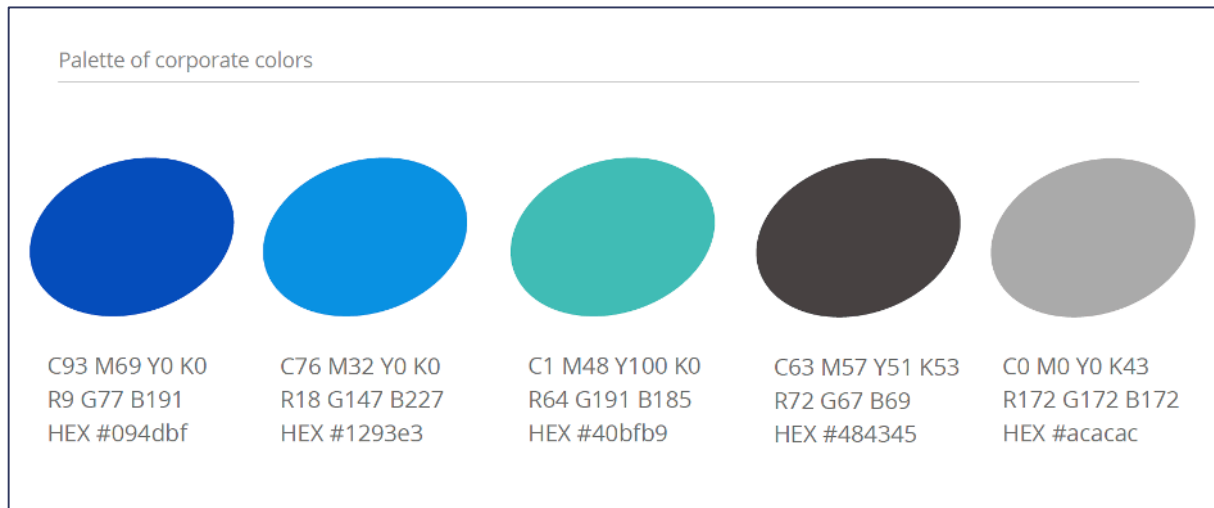


Figure 3: CYLCOMED palette of corporate colors

A general “brand guidelines” document has been developed and distributed to the partners since the beginning of the project to ensure a consistent look and feel in all of CYLCOMED’s communication activities. This is the base of a solid identity and facilitates the recognition of CYLCOMED wherever is presented. All dissemination materials refer to the project name, the project’s website and Horizon 2020 with associated graphic elements in line with the European Commission’s guidelines. The whole Brand Guidelines are in Annex 1 of this document.

A **PowerPoint presentation template** was created to be used by the partners to create their presentations for all external and internal events, meetings, etc., based on a common look and feel. The Appendix A gives an impression of the template.

EC acknowledgement

As an EC funded projects, CYLCOMED will clearly show the acknowledgement to the EC fund in all Dissemination & Communication materials (e.g., flyers, posters, brochures, video, website, etc). Below you will find examples of the elements to show in different positions.

2.8 Online tools and channels

2.8.1 Project website

The CYLCOMED project website is a fully functional site that offers comprehensive information on CYLCOMED’s aims and objectives, with easy access and a user-friendly interface for retrieving information and any public material generated within the project, as well as materials gathered via various work package activities about ongoing projects and relevant initiatives.

The CYLCOMED website serves as the entry point for the public and stakeholders (existing and newcomers) to the activities, services, material, and information that CYLCOMED is planning to create, collect, and share. Web design experts within the project consortium conceived its design and structure to promote the outcomes to the relevant target groups. The design of the website, developed on the WordPress platform, is strongly brand-oriented to consolidate the image of the CYLCOMED identity.

The dissemination material produced within the project and for interaction with social networks will use the website as a reference, ensuring consistent communication and an easy-to-recognize image/brand. To support multimodal access, it adopts responsive design principles aimed at providing an optimal viewing experience: the interface adapts the layout to the viewing

environment using fluid, proportion-based grids. The website will be publicly accessible from the first month of the project, with further updates applied promptly as necessary.

All the details about the website can be found in D7.2 – Project website.

2.8.2 CYLCOMED social media channels

CYLCOMED has established various social media channels to facilitate communication and dissemination of the project's activities and outcomes. The project has an active presence on popular social media platforms such as Twitter and LinkedIn. The social media channels are linked to the CYLCOMED website and will be used to promote the project's activities and outputs regularly. In addition, CYLCOMED plans to create a YouTube channel to release videos related to the project in Phase 2. The following is a brief overview of the social media channels created for CYLCOMED:

LinkedIn

The [CYLCOMED LinkedIn channel](#) is a professional social media designed to showcase the project's activities, progress and outcomes. It provides an opportunity for the project partners to connect with stakeholders and other professionals in the field of healthcare and medical devices. The channel will be regularly updated with news, project updates, publications, events, and other relevant information with tailored promotional materials. Using LinkedIn can have several positive outcomes for the CYLCOMED project, including:

- Building a professional network: LinkedIn is a valuable tool for building connections and expanding the project's network with healthcare professionals, medical device companies, policymakers, and other relevant stakeholders.
- Showcasing project achievements: Through regular updates and sharing of project progress and outcomes, the CYLCOMED LinkedIn channel can effectively promote the project and its achievements to a wide audience.
- Opportunities for collaboration: LinkedIn can facilitate collaboration with other professionals and organizations working in the same field, which can lead to joint projects, sharing of knowledge, and other mutually beneficial outcomes.

Overall, the CYLCOMED LinkedIn channel is an important tool for communicating and disseminating the project's outcomes and achievements to a wider audience and building valuable connections within the industry.

At the time of writing this deliverable (May 2023) the numbers of followers of the LinkedIn page is low, but the communication team and the partners envisage some activities that could potentially increase the number of followers for the CYLCOMED LinkedIn page:

1. Partners' presentation campaign: Introduce the consortium members to the general public with dedicated cards, quotes and interviews.
2. Share valuable content: Share informative and engaging content related to the CYLCOMED project on a regular basis. This could include updates on project developments, relevant news articles, and insights from project team members.
3. Use relevant hashtags: Incorporate relevant hashtags in your LinkedIn posts to increase visibility and reach. Some examples of relevant hashtags for the CYLCOMED project might include #healthtech, #medtech, or #healthcare, #eHealth #DigitalHealth #IoT #cybersecurity
4. Encourage project members to engage: Encourage all project partners to engage with the CYLCOMED LinkedIn page by sharing posts, commenting on updates, and inviting their connections to follow the page.

5. Promote the page on other channels: Promote the CYLCOMED LinkedIn page on other communication channels, such as the project website, email newsletters, and other social media platforms.
6. Leverage LinkedIn Groups: Join relevant LinkedIn groups related to the project's industry and share content from the CYLCOMED page within those groups. This can help to increase visibility and attract new followers who are interested in the project's topic.
7. Engage with other pages and accounts: Engage with other LinkedIn pages and accounts related to the project's topic by commenting on their posts and sharing their content. This can help to establish the CYLCOMED page as a thought leader in the industry and attract new followers who are interested in the project's topic.

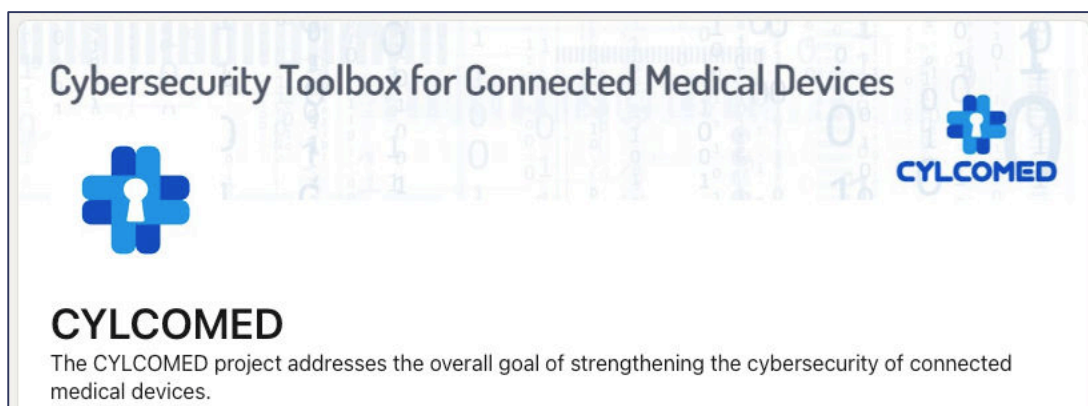


Figure 4: CYLCOMED LinkedIn page

Twitter

The CYLCOMED Twitter channel is a social media account created to promote the project's activities, outcomes and to engage with the target audience. Twitter is a popular social media platform that allows users to send and read short messages called "tweets". CYLCOMED's Twitter channel aims to provide regular updates about the project's progress, share relevant news and articles related to the project's topics, and encourage engagement with the project's followers. CYLCOMED's Twitter account, [@cylcomed](https://twitter.com/cylcomed), was set in December 2022 (M1). At the time of writing, it has **79 followers** and it has already reported on the project's kick-off meeting, the launch of the website and relevant initiatives.

The main outcomes of using Twitter for CYLCOMED are:

- Increasing visibility and awareness of the project: Twitter provides a quick and easy way to share information about the project with a wider audience. By regularly tweeting about the project's activities and outcomes, CYLCOMED can increase its visibility and attract more followers.
- Building a community around the project: Twitter allows for easy communication and interaction with the project's followers. By engaging with them and responding to their comments and questions, CYLCOMED can build a community of stakeholders who are interested in the project's topics.
- Sharing relevant news and articles: Twitter provides a platform for CYLCOMED to share news and articles related to the project's topics. This can help to establish the project as a thought leader in the field and attract more followers who are interested in the same topics.

- Driving traffic to the project website: By including links to the project website in tweets, CYLCOMED can drive more traffic to the website and increase the chances of visitors engaging with the project's content and becoming more interested in the project.

As a Horizon Europe project, CYLCOMED also follows the official Twitter account of the Horizon Europe programme @HorizonEU, joining the community of projects on social media. In compliance with the EC guidelines, we will tag @HorizonEU and @EU_Commission in our posts whenever we announce important news that clearly demonstrate the real impact of our research.

We will also use relevant hashtags, such as #DigitalEU, #horizoneurope, to expand the visibility of our communication and generate interactions of CYLCOMED's addressed topics. In addition, we will use other hashtags and accounts based on the content of the posts, including hashtags relevant to the project partners' organizations and representatives, hashtags of initiatives and events related to the project and the content, accounts of important participants in events, accounts of the Project Officer of the EC, and more.

To increase the reach and engagement of our Twitter channel, we will also implement the following activities:

- Regularly post updates, news, and insights related to the project
- Engage with other relevant Twitter accounts and participate in relevant Twitter chats and conversations
- Use multimedia content such as images, videos, and infographics to make our posts more engaging and visually appealing
- Share updates and posts from other related accounts to foster a sense of community and collaboration within the field
- Promote the Twitter channel on other project communication channels, such as the website and newsletter, to encourage more followers.

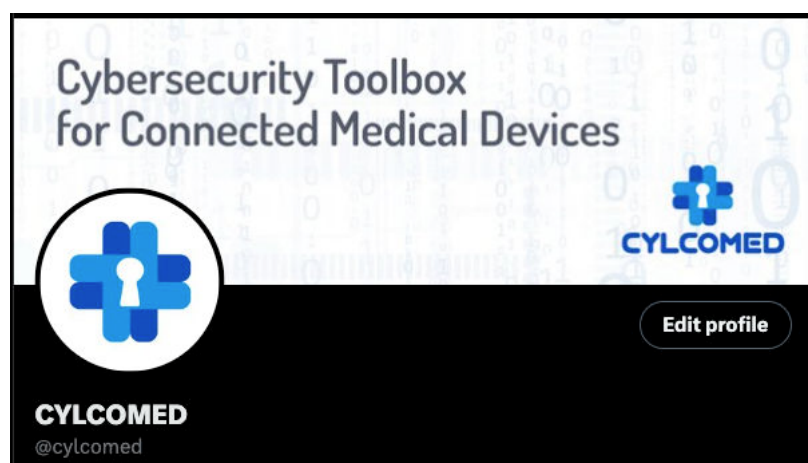


Figure 5: CYLCOMED Twitter page

Table 5: Social media accounts of the CYLCOMED consortium partners

SOCIAL MEDIA ACCOUNTS		
Partner	Twitter	LinkedIn
Charité – Universitätsmedizin Berlin	@ChariteBerlin	@Charité - Universitätsmedizin Berlin
Atos	@Atos @AtosES @ARI_Atos	@Atos
Mediaclinics	----	@MediaClinics
XLAB	@xlab_si	@XLAB
Martel Innovate	@Martel_Innovate	@Martel Innovate
Fundacion para La Investigacion Biomedica Hospital Infantil Universitario Nino Jesus	@fibhnjs	----
Ospedale Pediatrico Bambino Gesu	@bambinogesu	@Ospedale Pediatrico Bambino Gesù
RGB Medical Devices	-----	@RGB Medical Devices S.A.
Katholieke Universiteit Leuven	@KU_Leuven	@KU Leuven
INOV – Instituto de Engenharia de Sistemas e Computadores Inovação	@INOVinesc	@INOV

Table 6: List of the EU related Twitter and LinkedIn accounts

Organisation	Twitter account	LinkedIn account
Directorate General Communications Networks, Content and Technology (DG Connect)	@Digital_EU @Cybersec_EU	EU Digital & Tech

Directorate-General for Health and Food Safety (DG Sante)	@EU_Health	-
Horizon Europe programme	@HorizonEU	-
Joint Research Centre (JRC)	@EUScienceInnov	EU Science, Research and Innovation
European Health and Digital Executive Agency (HaDEA)	@EU_HaDEA	European Health and Digital Executive Agency (HaDEA)
European Union Agency for Cybersecurity (ENISA)	@enisa_eu	European Union Agency for Cybersecurity (ENISA)
European Institute of Innovation and Technology EIT Health	@EITHealth	EIT Health
HORIZON-HLTH-2022-IND-13 funded projects	<p>@NEMECYS_eu</p> <p>@EnTrust_Horizon</p> <p>@Septon_Project</p> <p>@hi_prix_horizon</p> <p>@xpanDH_project</p> <p>@ASCERTAIN_EU</p> <p>@SYNTHEMA_EU</p> <p>@aisym4med</p>	<p>NEMECYS Horizon Europe Project</p> <p>EnTrust Project</p> <p>n.a</p> <p>HI-PRIX HORIZON</p> <p>XpanDH Project</p> <p>ASCERTAIN</p> <p>Synthema</p> <p>AI Sym4MED - Horizon Europe</p>

Other social media channels

A Facebook account was not created as it is less valuable in terms of reach. The profile of Facebook users and its interactions, in fact, are less professional/research driven and less in line with the CYLCOMED communication targets and ambition. The YouTube channel will be open as soon as the first video is released.

2.8.3 The CYLCOMED newsletter

Regular updates about the CYLCOMED project's activities and progress will be shared with the public through our dedicated news channel hosted on the CYLCOMED website. Our team will issue a newsletter every 6 month and, if needed, newsflashes to keep our audience updated on the latest developments, major outcomes, and dissemination activities.

The newsletters will also include information about upcoming events and how to get in touch with the project and connected initiatives. The newsletter will be a collaborative effort with project partners contributing information and ensuring the content is accurate. All newsletters will be available on the project website, and a mailing list is being created based on

subscription. The CYLCOMED team will use GDPR-compliant and European-based solutions with a double opt-in feature to ensure data privacy. Interested visitors can already subscribe to the newsletter through the registration functionality available on the CYLCOMED website.

The first newsletter was released in May 2023 and is on the project website.

2.8.4 Publications

Significant project developments, news and announcements, white papers, but also articles introducing CYLCOMED will be published on third-party portals, including professional and specialised platforms, publications, Cordis, relevant thematic blogs and collaboration platforms, partners' websites, as well as through several freely accessible tools. Some of the people involved in this project have an academic background and have published several publications, in national and international publications.

For scientific publications, CYLCOMED project will guarantee 'green' open access (self-archiving) for scientific publications, granting free internet access to the submitted version of the research articles and full access to the published articles after any embargo period.

Table 7: Dissemination targets for publications

Peer-reviewed magazines/journals
IEEE Security & Privacy
Springer Security Journal
Elsevier Computers & Security
European Journal of International Security
Security and Communication Networks
IEEE Communications Magazine
IEEE Internet of Things
Journal of Cybersecurity

In addition, each CYLCOMED partner will identify target conferences/workshops for publication purposes.

2.8.5 Press releases

As a Horizon Europe project, CYLCOMED will develop press releases to highlight major project achievements such as the organization of significant events and the implementation of key project activities. These press releases will be disseminated in both national and European media outlets to increase the project's visibility. Each partner will be responsible for engaging with their local media to ensure wider coverage of the press release. All published press releases will also be available on the project website.

CYLCOMED's first press release was released on 9 March 2023. The release was distributed throughout Europe, with particular focus on the consortium partner countries which include Spain, Italy, Germany, Belgium, Switzerland and Portugal.

Media relations will cover a range of general and specialized media outlets, with a focus on those related to the Internet of Things, cybersecurity, health and technology.

2.9 Offline tools and channels

2.9.1 CYLCOMED promotional materials

A comprehensive set of communication and promotional mechanisms and tools will be established early on to properly support all the impact creation activities, tailored to the specific CYLCOMED objectives and targeted stakeholders.

Promo materials, both online and offline, will be produced for communication and dissemination purposes, presenting the project and its achievements, e.g. slides, posters, roll-ups, press releases, news, flyers, multimedia content, videos, photo galleries and giveaways.

2.10 Events

2.10.1 CYLCOMED trainings

CYLCOMED is dedicated to collaborating with all of the intended stakeholders, including manufacturers, suppliers, healthcare providers, integrators, and operators, to enhance the efficiency and quality of customized healthcare services. As the project's first consolidated results emerge, a series of training materials and workshops will be developed to involve stakeholders. The project will conduct training and knowledge-sharing activities that are linked to the planned use cases. The first training session will take place around M24, and the second around M33, engaging non-ICT end-users such as healthcare providers. Through these training sessions, stakeholders will learn about the CYLCOMED methodological and technical cybersecurity framework created for health solutions that depend on connected medical devices. The training sessions will be delivered in a hybrid format with both physical and remote participation and presentations, providing materials on the main concepts, instructions, and technical details discussed in documents, presentations, and video formats, which will also be publicly available on the project website.

2.10.2 Participation in events

The Consortium has already identified some key events to participate towards awareness, promotion and attraction of stakeholders.

Table 8: Cybersecurity/Health related events

Cybersecurity/Health related events
Cyber Security & Cloud Expo Global, The European Health Forum Gastein 2023 (October 4-6, 2023 in Bad Hofgastein, Austria), The Digital Health Conference 2024 (February 13-14, 2024 in Berlin, Germany), Medica Fair (November 13-16, 2023 in Düsseldorf, Germany), Internet of Things Solutions World Congress (October 23-25, 2024 in Barcelona, Spain), European Cybersecurity Month: This annual campaign takes place throughout October 2024, promoting cybersecurity awareness and best practices across Europe, Health and Medical Informatics Conference (HMiC) - August 15-17, 2024 - Prague, Czech Republic, ICHIST 2024: 18. International Conference on Healthcare Information Systems and Technology (July 08-09, 2024 in Prague, Czech Republic), International Conference on e-Health and Healthcare Innovations (ICeHHI) - November 25-27, 2024 - Lisbon, Portugal, International Conference on Information and Communication Technologies in Health (ICTH) - December 16-18, 2024 - Dublin, Ireland.

2.11 Synergies and interaction with external initiatives

Dedicated efforts will focus on the establishment of partnerships with relevant ongoing initiatives and networks, engaging key players from all groups of the defined stakeholders across the relevant domains of health and cybersecurity. The ambition is to ensure awareness creation and engagement of target stakeholders into the uptake of CYLCOMED technologies and concepts. A special focus will be given to Horizon Europe ongoing projects funded under the same topic (HORIZON-HLTH-2022-IND-13-01 - Enhancing cybersecurity of connected medical devices) and call (HORIZON-HLTH-2022-IND-13).

As appropriate, the partners are planning to participate in key/flagship events presenting the project results and networking and invite representatives of such players to the workshops and events being organised by the project.

Thanks to participation of many partners to several ongoing projects, associations, initiatives and networks, targeted liaisons and synergies will be fostered to ensure CYLCOMED's broad outreach, fostering effective CYLCOMED uptake and validation. These initiatives and organisations will constitute the basis of the broader CYLCOMED ecosystem. CYLCOMED will build synergies starting early in the project and throughout the entire implementation, following the designed dissemination and communication strategy and plan, taking advantage from partners memberships to and synergies.

Projects working funded under the same call:

- **ASCERTAIN** Affordability and Sustainability improvements by using new pricing, Cost-Effectiveness and Reimbursement models to Appraise iNnovative health technologies
- **AI-Sym4MED** Synthetic and scalable data platform for medical empowered AI
- **XpanDH** Expanding Digital Health through a pan-European EHRxF-based Ecosystem
- **MEDSECURANCE** Advanced Security-for-safety Assurance for Medical Device IoT
- **NEMECYS** NEw MEdical CYbersecurity assessment and design Solutions
- **SYNTHEMA** Synthetic generation of hematological data over federated computing frameworks
- **SHIFT-HUB** Smart Health Innovation & Future Technologies Hub
- **SEPTON** Security protection tools for networked medical devices
- **SECURED** Scaling Up secure Processing, Anonymization and generation of Health Data for EU cross border collaborative research and Innovation
- **ENTRUST** ENSuring Secure and Safe CMD Design with Zero TRUST Principles
- **HI-PRIX** Health Innovation Next Generation Payment & Pricing Models

The collaboration with these projects will happen on several levels including, but not limited to:

- Co-organisation of events.

- Exchange of information related to project achievements.
- Mutual promotion: dissemination and communication using social media and online presence tools.
- Interviews with key stakeholders.
- Invitation for participation in CYLCOMED events, and vice versa.
- Collaboration on other publications.

2.12 Communication and dissemination impact assessment

By implementing the CYLCOMED Communication and Dissemination plan and strategy we expect to communicate certain relevant knowledge and outcomes to each of the target groups, as well as to attract their interest and generate engagement that will influence the overall impact of the project. The complete set of communication and dissemination activities will be closely monitored and evaluated by the WP7 lead in order to keep track of all ongoing activities. D7.3 – Dissemination, Communication, Standardisation and Exploitation Initial Report and D7.4 – Dissemination, Communication, Standardisation and Exploitation Final Report (M18 and M36) will document all the related conducted activities.

The evaluation of the communication strategy uses a set of metrics that will be used to monitor and assess the progress of the communication activities and measure their impact by WP7, as summarized in the table below. This will allow corrective measures to be taken and enforced, whenever needed – notice this list might be enriched at project run-time. Process evaluation will involve examining the progress of the strategy's implementation and will refer to an outreach activity that is quantifiable through the attendance of persons present from the audiences, number of events participated in, the development and dissemination of messages and materials, media presence and traffic created in social media.

There are various key issues associated with measuring and controlling the outreach and impact creation strategy and plan. Achievement is often more difficult to measure and compare, and thus needs to be carefully quantified and measured according to the specific type of action involved. The objectives chosen must be realistic, clearly defined, relevant, and coherent; the means of measurement must be objective, clearly defined and quantified, and the measurement process must not involve significant levels of cost relative to the objectives themselves. The evaluation needs to be continuous or incremental as much as possible, in particular for non-repetitive actions. Finally, the measurement of different actions must allow some degree of comparison with other actions and/or alternatives.

In full accordance with the CYLCOMED needs, we take on a five-step measurement cycle model, spanning from objective identification to data driven optimisation:

- We identify our core objectives (e.g., raise awareness, increase engagement – i.e., acquire more contacts, acquire more participants to our events).
- We set goals for our promotional tactics. We concentrate on how to accomplish our objectives (e.g., inform visitors through the content of our website, intensify events promotion, etc.).
- We identify our Key Performance Indicators (KPIs) – the metrics that play a crucial role to the success of the aforementioned utilized tactics and set the expected achievable targets.

- We measure the progress and impact of the conducted activities based on these metrics on a regular basis. Such metrics will allow us to have a constant view of the amount and the effectiveness of the dissemination activities conducted.
- We adjust and optimise the communication strategy towards achieving the expected outcomes and maximising visibility.

The tools, products and activities outlined in this strategy will be monitored, measured, evaluated and realigned on an ongoing basis.

Table 9: Communication and dissemination KPIs

Measure	Indicators and Target (M36)	Results at M06
Project website	N° of unique visitors to the website: 1500 (average per year)	171
Flyers	N° of flyers: 6	-
Posters/roll-ups	N° of posters/roll-ups: 4	-
Social Networks	Project accounts on Twitter and LinkedIn: ≥ 1,000 connections/followers in total; ≥ 60 posts on social networks	68 connections 8 posts
Videos (including motion graphics explainer video)	≥ 6 online videos	-
Press releases	≥ 4 press releases	1
Newsletters	≥ 6 newsletters (one every 6 months)	1
Multimedia training materials	12 multimedia items	-
Participation in workshops, fairs, conferences and other events (in person or online)	≥ 8 fairs and conferences where beneficiaries will take part and present CYLCOMED concept, results and demos.	-
Training workshops (in person or online)	≥ 2 training workshops with 40 stakeholders attending each workshop.	-
Workshop for developers	Workshop for developers organised in Y3 with ≥ 30 participants	-
Publications	≥ 12 articles, including scientific publications (peer-reviewed and open access preferred) with an impact factor greater than 1,5	-



3 STANDARDISATION STRATEGY AND PLAN

3.1 CYLCOMED standardisation mission

In CYLCOMED we intend to identify and comply with those standards that are more significant for those specific methods and tools developed/ used by partners. The deliverable presents a preliminary plan to study in more depth the specific standards, learn the current development status of applicable standards and discuss possibilities of improvements. Through identification of specific standardization groups that could be approached and influenced by the project partners, proposals of improvements of those standards will be evaluated based on the results generated by the project partners in the remaining two years of the project.

The way partners can be related to a specific standard is: i) at system level, e.g., on the tools or methods for the verification of requirements for the implementation of a use case demonstrator, or ii) at component level, e.g., the hazard analysis methodology or FMEA tool that a Cylcomed partner uses in compliance with a specific standard.

Taking into consideration all tools used in Cylcomed, and the specific tools/methods developed/improved, we intend to identify those standards that are more significant; then, this deliverable will draw a plan to study in more depth the specific standards and learn on their current status and possibilities of improvement.

3.2 First review for identification of applicable CMD Cybersecurity standards

A preliminary work has been done in order to identify applicable standards in the medical domain, and in particular in the cybersecurity area. There is a survey in which partners are being asked their current involvement with these standards or others not yet considered. The following identified standards are shown in the table below:

Table 10: Identified applicable standards

Standard	Comment
ISO 13485	This standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
IEC TR 63069	Framework for the interaction from safety to security on a domain independent level.
ISO/IEC 20543:2019	Test and analysis methods for random bit generators within ISO/IEC 19790 and ISO/IEC 15408; for the use of hardware security modules and cryptographic tools in IoT applications and information management systems.
ISO/IEC JTC1 SC42 TR 24028	Overview of trustworthiness in AI (Artificial intelligence) (under development)

ISO/IEC 23053	Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML) (under development)
ISO 29100	Higher-level framework for securing Personally Identifiable Information (PII) with Information and Communication Technology (ICT) systems.
ISO/IEC 27550 TR	Privacy engineering for system life cycle processes.
EN 80601-2-30: 2010.	Particular Requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers". This standard specifies particular requirements related to the measurement of non-invasive blood pressure.
EN 62304:2006 and EN 62366:2008	Although the general standard covers these aspects, there are two specific standards that must be applied: · The first one: Medical device software - Software life cycle processes · The second one Medical devices - Application of usability engineering to medical devices. All the aforementioned standards have also several amendments since their approval and are permanently revised. The EN 62304 standard requires to follow the well-known V-model for the software life cycle processes of a medical device, but the rest of standards normally include specific requirements not related with the product life cycle.
IEC 62304	International Electrotechnical Commission (IEC), «IEC 62304. Medical device software – Software life cycle processes,» 2006. Specifies life cycle requirements for the development of medical software and software within medical devices.
IEC 62366-1	International Electrotechnical Commission (IEC), «IEC 62366-1. Medical devices - Part 1: Application of usability engineering to medical devices,» 2015. Usability Engineering.
ISO 26262	ISO 26262 Edition 2 was published in 2018 and focuses on functional safety for automotive systems. It could be applied to vehicles in the farming domain and the interaction with security (e.g. combining V&V) is included.
EU Medical Device Regulation (MDR) 2017/745	A new medical device regulation was approved in 2017 ; , amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
(EU) 2017/746	(EU) 2017/746 as regards the transitional provisions for,» 2023..
(EU) 2017/746	Regulation of the European Parliament and of the Council, «Regulation (EU) 2017/746. In Vitro Diagnostic Medical Devices,» 2017.

(EU) 2023/607	Regulation of the European Parliament and of the Council, «Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for,» 2023..
IEC 80001	Addresses safety, effectiveness and data and system security for networks incorporating medical devices.
ISO/IEEE 11073	Interoperability between Medical Devices
93/42/EEC	Current medical devices directive. The link to the harmonized standards is: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en
IEC 60601-x-y/IEC 80801-x-y	IEC 60601 series and IEC 80601 series are standards for many types of medical electric equipment (devices) safety and essential performance (electric and electronic aspects, including surgical and rehab robots); part 60601-1). IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, is the general medical devices safety standard.
EN ISO/IEC 60601-1-x.	Collateral standards
EN 60601-1:2006	Main standard for this Use Case, with the title "Medical Electrical Equipment. General Requirements for basic safety and essential performance".
EN 60601-1-2: 2007.	Collateral standard: Electromagnetic compatibility.
ISO 60601-4	Usability Engineering.
IEC/TR 60601-4-5	Medical Electrical Equipment – Part 4-5. Safety related technical security specifications for medical devices. This standard provides detailed technical information for security features in medical devices used in medical IT networks.
EN 60601-1-6: 2010	Collateral standard: Usability.
EN 60601-1-8: 2007.	Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
EN 60601-1-10: 2008.	Collateral standard: Requirements for the development of physiologic closed-loop controllers.
EN 60601-2-10:2015	Also there are particular standards related with the general standard, that are related with the safety of a specific medical device. The particular standards applicable to this use case are:
EN ISO 14971	Risk Management (Product). Mentioned in Task 7.3 of Cylcomed

EN ISO 27779	Mentioned in Task 7.3 of Cylcomed
EN ISO 62304	Software Lifecycle.
EN ISO 31000	Risk Management (Organisation) or particular standards under ISO 31xxx.
EN ISO/IEC 27000	Information technology — Security techniques — Information security management systems (ISMS) — Overview and vocabulary.
EN ISO/IEC 27001	Information Technology – Security techniques – Information Security management Systems – Requirements.
EN ISO/IEC 27002	This document provides a reference set of generic information security controls including implementation guidance.
ISO/IEC 80001-1	Application of Risk Management for IT networks Incorporating Medical Devices.
ISO/IEC 80001-5-1	Application of Risk Management for IT networks incorporating medical device – Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software – Part 5-1: Activities in the product life-cycle.
IEC/TR 80001-2-2	Application of Risk Management for IT networks Incorporating Medical Devices Part 2-2: Guidance for the Disclosure and Communication of Medical Device Security Needs, Risks and Controls.
IEC/TR 80001-2-8	Application of risk management for IT-networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2.
ISO/IEC 80001-xx	including IEC/TR 80001-2-1, IEC/TR 80001-2-3, IEC/TR 80001-2-4, IEC/TR 80001-2-5, ISO/TR 80001-2-6, ISO/TR 80001-2-7 or other
IEC 82304-1	Health Software Part 1: General requirements for Product Safety.
MDCG 2019-16	Medical Device Coordination Group EU, «MDCG 2019-16. Guidance on Cybersecurity for medical devices,» 2019.
(EU) 2016/679	Regulation of the European Parliament and of the Council, «Regulation (EU) 2016/679. General Data Protection Regulation (GDPR),» 2016.
The EU Cybersecurity Act	European Commission, «The EU Cybersecurity Act,» [En línea]. Available: https://digital-strategy.ec.europa.eu/en/policies/cybersecurity-act .

ISO 27799	International Organization for Standardization (ISO), «ISO 27799. Health informatics — Information security management in health using ISO/IEC 2700,» 2016-07.. By implementing ISO 27799, healthcare organizations and other custodians of health information will be able to ensure a minimum requisite level of security that is appropriate to their organization's circumstances and that will maintain the confidentiality, integrity and availability of personal health information in their care.
(EU) 2022/2555 (NIS2)	Regulation of the European Parliament and of the Council, «Directive (EU) 2022/2555 (NIS2). Measures for a high common level of cybersecurity across the Union,» 2022.
The Cybersecurity Act	European Commission, «The Cybersecurity Act strengthens Europe's cybersecurity,» [En línea]. Available: https://digital-strategy.ec.europa.eu/en/news/cybersecurity-act-strengthens-europes-cybersecurity .
The Cybersecurity Act	European Commission, «Questions and Answers - EU Cybersecurity,» [En línea]. Available: https://ec.europa.eu/commission/presscorner/detail/en/QANDA_19_3369 .
FDA	Food and Drug Administration (FDA), «Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions,» 2022.
IMDRF/CYBER WG/N60	International Medical Device Regulators Forum (IMDRF), «IMDRF/CYBER WG/N60. Principles and Practices for Medical Device Cybersecurity,» 2020.

3.3 CYLCOMED standardization strategy and plan

The following activities are proposed, to be carried out during the timeframe of the project:

3.3.1 Monitoring of participation of partners in SDOs

An Excel file will be set up for monitoring the participation of partners in Standards Development Organizations (SDOs). The excel sheet will make it possible to add, maintain its content, and define specific actions or follow-ups on the activities. Partners will be asked to update the Excel file continuously, every time they participate in SDOs sessions. **Fehler! Verweisquelle konnte nicht gefunden werden.** shows the type of information requested.

Table 11: Tracking of standardisation activities

Date	i.e. 15 th -05-2023
Type of activity	i.e. Working group meeting
Title	i.e. ref to doc of specific standard

Related standard	
Working Group	
Active Party	Member of Cylcomed
Person involved	(optional)
Summary of activity	Purpose and content
Suggested follow up activities	
Topics discussed that may be relevant for Cylcomed	
Activities of Cylcomed relevant to the topics discussed in the standardization group.	

We find it important to show that partners were active in standardization and to foster the exchange between project partners. The results of partners participation will be presented by the end of the project in D7.4.

3.3.2 Training Sessions about relevant standards

The consortium will allocate time and effort on a series of training sessions on relevant standards used in different tools/methods/use cases, in order to bring awareness to Cylcomed partners about the existence of such standards. Invitations to a standardization presentation will be sent at least 2 weeks in advance. The purpose is to try to collect as many attending partners as possible. One of the most interesting outcomes of these meetings is to receive feedback from the rest of the partners about the way a standard could be applicable in a particular application, and to promote the active participation of partners in the SDOs. These sessions will be recorded and available for the project partner who could not join and used for dissemination purposes.

The gap analysis on SCP V&V methods, tools and concepts detailing strengths and weaknesses of the applicable standards will be taken into consideration in the course of the following months. A gap analysis of such standards will be carried out as the training sessions of selected standards are being presented to the Cylcomed partners. This will allow to send specific messages to SDOs.

3.3.3 Collection of surveys on standard related issues

Some surveys will be distributed to all partners in the elaboration of deliverables D7.3. with the purpose to collect information on the relation of partners with particular standard related issues. It is important to identify their availability to participate/ influence in a particular SDO, in relation to a particular standard. These surveys will be used as a tool in the forthcoming months to gain deeper knowledge on specific standard related issues.



4 EXPLOITATION STRATEGY AND PLAN

Task 7.2 is dedicated to the exploitation actions partners are expected to complete focused on the commercial viability of the main outcomes. It will consider new business and operating models for bringing the project results to customers considering how obligations under the new Medical Device Regulations can act as catalyst to drive demand for cybersecurity tools (covering risk management and security controls) that CYLCOMED will deliver as project results. This task puts a strong focus on how all stakeholders can profit from the exploitation of the results, and develop a timeline for exploitation, identifying the prospective time frame after the end of the project to bring the results to the market. It will manage the IPR, knowledge management and business planning. CYLCOMED, as a research and innovation project, will explore different types of output:

- 1) Increased knowledge and expertise which produces “competency impacts”;
- 2) New or increased knowledge that affects the future performance of the related industries;
- 3) Results which could lead to direct economic benefits (development, creation and marketing of products, services or processes).

A catalogue of the CYLCOMED results will be set up and an exploitation plan at the mid-term of the project, which will be updated at the end of the project. Identification of necessary subsequent research projects, and opportunities for co-funding (at European or National Levels) will be investigated by partners for each key exploitable result identified.

4.1 Exploitation objectives

Therefore, this deliverable aims to create a business and exploitation plan that will explore the potential for the development and exploitation of the methods implemented after the achievement of the Cylcomed project. All partners are involved in the exploitation activity by evaluating the potential use, marketability and the applicability of the key concepts and ideas for the evolution of the tools, methods or use cases.

This deliverable is intended to:

- Present a preliminary exploitation plan for the project and provide holistic overview of the exploitation landscape surrounding it;
- Set up a survey to identify the markets and sectors that are relevant in the context of exploitation, and to emphasise the importance of analysing their role, needs and potential;
- Serve as a step towards setting out clear and measurable exploitation targets, whose results will be monitored and reviewed regularly;
- Serve as a guidance document for Cylcomed project partners and to stimulate exploitation engagement among partners;
- Ensure that exploitable entities will be deployed in an optimal way and that the desired impact is achieved;
- Act as preliminary document that will be developed further in the following years.

The main objective for exploitation in VALU3S is to implement an exploitation strategy to facilitate the successful exploitation and adoption of results and benefits within V&V methods and tools to reduce the time and cost needed to verify and validated automated systems with respect to SCP requirements.

Exploitation is referred by the EC as the utilisation of results in further research activities other than those by the action concerned or in developing, creating and marketing a product or process, or in creating and providing a service, or in standardisation activities [1].

The meaning of the word “results” in this context is broad, and refers to any tangible or intangible output of the action, such as data, knowledge and information whatever their form or nature, whether or not they can be protected, which are generated in the action as well as any attached rights, including intellectual property rights [1].

The VALU3S exploitation and business impact task (Task 6.2) aims to explore and define the potential for the development and exploitation of the project results and to plan the following exploitation process.

Based on this requirement, VALU3S Task 6.2 aims to address exploitation in a coherent manner throughout the project and to support the beneficiaries in eliciting and coordinating their exploitation strategies, thus increasing the chances for the results of the project to become, through appropriate exploitation measures, innovations that can produce tangible benefits and satisfy specific needs and wants.

The main objective for exploitation in Cylcomed is to implement an exploitation strategy to facilitate the successful exploitation and adoption of results and benefits within security methods and tools to reduce the cybersecurity risks in CMDs with respect to SCP requirements.

The Cylcomed exploitation and business impact task (Task 7.2) aims to explore and define the potential for the development and exploitation of the project results and to plan the following exploitation process.

Based on this requirement, Cylcomed Task 7.2 aims to address exploitation in a coherent manner throughout the project and to support the beneficiaries in eliciting and coordinating their exploitation strategies, thus increasing the chances for the results of the project to become, through appropriate exploitation measures, innovations that can produce tangible benefits and satisfy specific needs and wants.

4.2 Consortium exploitation plan

The first step of the process is intended to support the partners in identifying the exploitable results they are interest in and in defining their exploitation strategy. Likewise, it also intends to carry out a preliminary analysis of each of the tools/methods/use cases that will be addressed in the project through a Canvas business model. A specific survey for data collection has been designed for this purpose by the team in charge of the exploitation task (RGB) and shared with the other partners.

After identifying the contribution that each participating entity intends to provide in the implementation of this initial exploitation plan, information will be collected in the following months from each of the companies. This information, as aforementioned, will be updated and worked on in greater depth throughout the project, as the methodologies addressed are detailed.

This process is based on questionnaires that aim to cover all the fields in which Cylcomed parties contribute, so that the information obtained is structured and detailed identically for each of the contributors. The document is a specific document where each contributor is asked to identify which results of the project they consider exploitable, as well as their market-oriented activities. The second document is a study of the specific tools/methods/use cases that will be worked on during the project. In order to structure all the individual exploitation strategies of Task 7.2 contributors, and support the partners in better describing their strategy according to the domain they intend to address, they are requested to declare:

CYLCOMED will provide a methodological and technical cybersecurity framework designed for healthcare services that use CMDs. We are interested to identify the real key exploitable result of each of the consortium partners.

The methodology to be followed for the individual market analysis of each of the CYLCOMED partners is based on:

1. Identification of the results (assets) that each partner will obtain
2. the market share that the organisation will cover
3. the market analysis for that market share
4. The key market drivers, market trends, target user profiles (their interests and preferences), the competitors that your organisation will have
5. what value will their value proposition is compared to yours
6. Which stakeholders should be analysed.

4.2.1 Results identification for every partner

A second survey document will ask each use case leader (and their contributors) to identify the key partnerships, key resources, key activities, value propositions, customer relationships, channels, customer segments, cost structure and revenue streams of their use case. The collected information will take into account the fact that deliverables 7.3 and 7.4 are “public”.

The second step of the methodology will be dedicated to consolidating the exploitation strategy of the project. In this phase, the exploitation plans will be revised and updated at individual level, based on the collected information.

The output produced at the end of the process will be the final exploitation activity report and short/long-term market analysis presented in M36, at the end of the Cylcomed project.

4.2.2 Business model for each use case

The goal of exploitation in VALU3S is to ensure the sustainability of the project’s results beyond the project’s lifetime and to demonstrate how VALU3S can influence the EU landscape. Exploitation includes multiple forms:

- **Financial exploitation**, by developing products, projects, or services based on the project results.
- **Research and development**, by engaging new products (EU-funded or sponsored by other sources), based on the experiences gained in the project.
- **Education**, e.g. via course offerings, at the university level or in continuing education.
- **Community-building** around the topics of the project, raising awareness for the problems addressed and the proposed solutions.
- **Knowledge transfer**, from academia to industry, by collaboration or via employees.
- **Contributions to open-source projects and standardization**, providing public access to the framework and encouraging its broad adoption in commercial and public systems for interested parties.



As a main result, the Cylcomed project is expected to follow a generic plan, regardless of the domain being worked on, for the industrialization of the newly developed technology and a business plan for future commercial exploitation. This is the base for a draft business plan for future commercial exploitation.



5 CONCLUSIONS

This deliverable on Dissemination, Communication, Standardisation, and Exploitation Strategy and Plan demonstrates the CYLCOMED project's commitment to effectively disseminate its outcomes, foster communication among stakeholders, engage in standardization efforts, and lay the foundation for successful exploitation of its results.

The project has established robust communication mechanisms, utilizing a range of tools and platforms to engage stakeholders, provide regular updates, and encourage dialogue within the field. Through a dedicated project website, newsletters, social media, and press releases, CYLCOMED effectively communicates its progress, achievements, and the significance of its work to a broader audience.

Furthermore, the project has recognized the importance of standardization and has actively engaged in relevant standardization groups. By identifying and assessing applicable standards, proposing improvements, and participating in standardization activities, CYLCOMED has contributed to shaping industry standards and ensuring the alignment of its cybersecurity framework with existing regulations and requirements.

Looking ahead, the project has laid the groundwork for successful exploitation and commercialization of its results. By developing an exploitation strategy, conducting market analyses, and identifying key exploitable results, CYLCOMED partners are well-positioned to leverage their research outcomes and drive their adoption in the market. The project's focus on business planning, intellectual property management, and the identification of subsequent research opportunities further reinforces its commitment to realizing the full potential of its results.

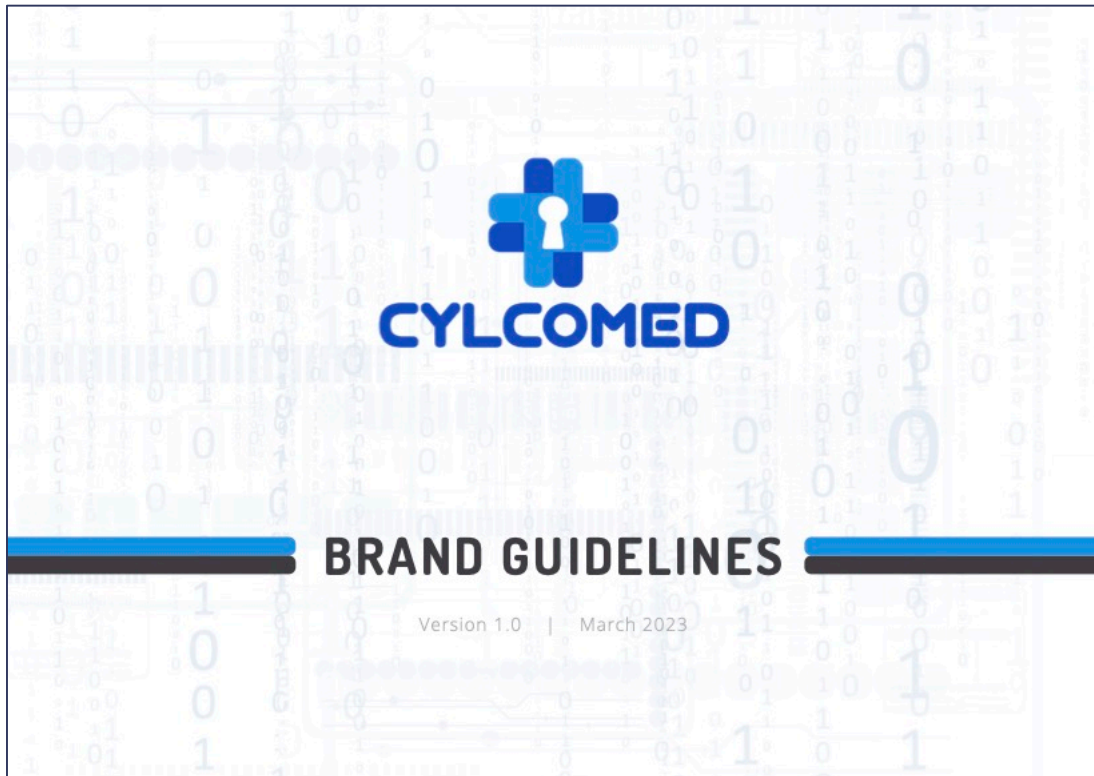
By effectively disseminating its outcomes, engaging stakeholders, contributing to standardization efforts, and preparing for exploitation, the project is poised to make a significant impact on the cybersecurity of Connected Medical Devices. Through its collaborative efforts, CYLCOMED aims to enhance patient safety, protect healthcare infrastructure, and drive innovation in the field of medical device cybersecurity.

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6 Appendix


6.1 CYLCOMED Brand Guidelines

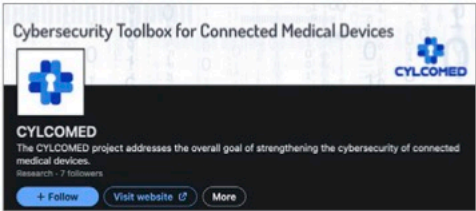


WHAT IS A BRAND IDENTITY?

A brand identity allows you to recognize a consistent look and feel across all outlets (electronic and printed visual media). It defines how those who come into contact with the brand should perceive it and influences their opinion of the brand. This document lists and explains the visual identity elements of the CYLCOMED project. These are rules and values to help you create and compose visual designs using its identity.

Examples of CYLCOMED's brand identity across different outlets (Twitter and LinkedIn accounts, website).






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LOGO

Main version of the CYLCOMED logo with some basic recommendations.


Main version




Clear zone



Icon version (for social media outlets)



Minimum size




10 mm

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LOGO VARIATIONS

The main logo is also provided in the variations depicted here below, to allow readability over dark backgrounds or for black and white printing purposes.


Grey shades version



Negative version



Horizontal version




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DOS AND DONT'S

Basic instructions on how to use the main logo - and its variations - over diferent types of backgrounds.

Dos




Negative version on high contrasted background colour




Main version on image background assuring high contrast

Don'ts



Not enough contrasted background



Not enough contrasted background






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CORPORATE COLOURS

A main palette of two colours based on the logo colour scheme plus a third complementary and warmer colour to highlight elements. Two more complementary greyscale colours complete the full CYLCOMED colour palette.

For slide presentations and deliverables: the colour of standard elements has been defined and locked in the respective templates, as those documents are likely to be mainly edited outside design departments. To change colours (icons or additional text), editors will find the corporate color palette in the templates.

Palette of corporate colors

				
C93 M69 Y0 K0 R9 G77 B191 HEX #094dbf	C76 M32 Y0 K0 R18 G147 B227 HEX #1293e3	C1 M48 Y100 K0 R64 G191 B185 HEX #40bfb9	C63 M57 Y51 K53 R72 G67 B69 HEX #484345	C0 M0 Y0 K43 R172 G172 B172 HEX #acacac

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FONT TYPES

CYLCOMED's brand uses the open source fonts Dosis bold for headings and Open Sans for the body copy.

This applies to the website and all promotional material.

For presentations and deliverables, the system font Calibri (only Regular and Bold versions) should be used instead to avoid missing font issues, as those documents are likely to be mainly edited outside design departments.

Headings (to be used on the website and all promotional material)

Dosis bold
 ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
 1234567890

Body copy (to be used on the website and all promotional material)

Open Sans regular
 ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
 1234567890

Open Sans bold
 ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
 1234567890

Alternative Body copy and headings (to be used for presentations and deliverables)


Calibri regular
 ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
 1234567890

Calibri bold
 ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
 1234567890


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EC ACKNOWLEDGEMENT

All the EC funded projects should clearly show the acknowledgement to the EC fund in all Dissemination & Communication materials (e.g. flyers, posters, brochures, video, website, etc). Below you'll find a few examples of the elements to show in different positions.




Co-funded by
The European Commission



Co-funded by
The European Commission

Co-funded by
The European Commission



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A slide with a light blue background featuring a faint pattern of binary code (0s and 1s) and circuit-like lines. At the top center is the CYLCOMED logo. Below it, the word "CONTACTS" is written in a bold, black, sans-serif font. Underneath, there are two paragraphs of text. The first paragraph provides contact information for Miguel Alarcón. The second paragraph states that all graphic assets are available in a repository. At the bottom center, there is a small European Union flag icon followed by text indicating funding from the Horizon Europe programme.

CYLCOMED

CONTACTS

For any questions regarding the CYLCOMED graphic assets and the uses you would like to make of them, do not hesitate to contact Miguel Alarcón at Martel Innovate:
miguel.alarcon@martel-innovate.com

All CYLCOMED graphic assets, including this brand guidelines and the fonts, can be downloaded on the repository of the project.



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