‘COMBINE’ programme strategy

Table of Content

Abbreviations

CI	Clinical investigation (of a medical device)
CIE WG	Clinical investigation and evaluation working group (sub-group of MDCG)
CT	Clinical trial (of a medicinal product)
CTAG	Clinical Trials Coordination and Advisory Group
CTCG	Clinical Trials Coordination Group
CTR	Regulation (EU) 536/2014 on clinical trials
EMA	European Medicines Agency
IVD	*in vitro* diagnostic medical device
IVDR	Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices
IVD WG	In vitro diagnostic medical devices working group (sub-group of MDCG)
MedEthicsEU	Forum for Ethics Committees of both medicines and devices in EU
MRECs	Medical research ethics committees
MDCG	Medical Device Coordination Group
MDR	Regulation (EU) 2017/745 on medical devices
NCAs	National competent authorities
OKR	Objectives and key results
PS	Performance study (of an *in vitro* diagnostic medical device)

1. Background

In the EU, there are legal requirements for the individual authorisation processes of clinical trials (CT) of medicinal products, clinical investigations (CI) of medical devices and performance studies (PS) of *in vitro* diagnostic medical devices (IVDs). These requirements are laid out in Regulation (EU) 536/2014 on clinical trials of medicinal products for human use (CTR), Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) respectively. In practice, these Regulations may need to be applied together to develop innovative treatments combining medicinal products with medical devices or IVDs. As part of this development, **combined studies** may be carried out.

Combined studies can be understood as studies that involve the simultaneous investigation of a medicinal product, an IVD and/or medical device which are subject to the requirements of the CTR, IVDR and/or MDR. A combined study may also involve more than one medicinal product or more than one medical device/IVD. Examples of combined studies are a clinical trial of a medicinal product in parallel with a performance study of an IVD, or a clinical trial of a medicinal product in parallel with a clinical investigation of a medical device.

Member States' competent authorities for clinical trials for human medicinal products and medical devices and the European Commission launched the **COMBINE project** in June 2023. It aims to analyse the root causes of the challenges encountered by sponsors in conducting combined studies and identify possible solutions to these challenges.

The project involves representatives of medicinal products and medical devices competent authorities, the European Commission, medical research ethics committees, the European Medicines Agency and relevant medicinal product and medical device sector stakeholders. The Member State groups affiliated with this project are the Medical Device Coordination Group (MDCG) and relevant clinical trial groups: Clinical Trials Coordination Group (CTCG) and Clinical Trials Coordination and Advisory Group (CTAG)).

From its beginning, the project was envisaged to consist of two phases:

1. analysis of the challenges at the interface of MDR/IVDR/CTR.
2. possible development of solutions that aim to address some of the challenges.

The **analysis phase** was carried out between September 2023 and May 2024. It consisted of three analysis strands:

1. collecting and analysing the challenges reported by various actors involved;
2. mapping relevant national processes and;
3. mapping already ongoing work in this area.

In addition, a fourth strand brought the above three parts together and presented proposals for possible solutions to address the identified issues.

The analysis phase was structured in a project management framework, with the ‘steering board’ giving overall direction, the ‘project group’ carrying out the work with the involvement of the ‘stakeholder group’, the ‘project manager’ ensuring liaison between all these entities and the

'reference groups' (MDCG and CTAG) endorsing the outcome. The analysis phase resulted in a report which was published on 14 May 2024[1].

2. The approach to the development of the COMBINE programme

With the analysis phase completed, the project is moving into its **second phase** – the development and implementation of solutions. This second phase requires careful planning for a variety of reasons. A large number and diversity of issues (a total of 78) as well as of the proposed actions to address them (over 50) were identified in the analysis phase. Different actions have different time scales and, in many cases, a logical order in which they should be carried out. A significant number of actions are already ongoing. These must be consolidated and prioritised going forward, taking into account also the broader context of each sector. Secondly, there are different groups involved, each of which have their decision-making mechanisms, priorities and working methods. It must be considered how the actions should be carried out in practice, who are or will be the entities primarily responsible for each of them and how to ensure a cross-sectorial approach while using resources in the most efficient way. While the analysis phase was essentially a single project involving discussion and production of a report, the second phase introduces a new level of complexity, requiring coordination on multiple projects managed by various groups.

Taking the above into account, the second phase of COMBINE is better framed as a **programme**, i.e. a set of interlinked projects and collaborating groups.

This document describes the **programme strategy**: it clarifies the vision, the structure and governance, overall plan of activities, the ways of working and approach to evaluation of the activities in the second phase of COMBINE.

3. COMBINE programme vision

The vision statement for the COMBINE programme is as follows:

> The COMBINE programme seeks to make the European Union an attractive region to conduct combined studies, envisioning a clear and smoothly functioning regulatory environment for combined studies through broad involvement of regulators, ethics committees and all impacted stakeholders, with the ultimate goal to support availability of innovative treatments for patients.

4. Parties involved

Medical devices are governed at a European level by the EU Commission expert group, the Medical Device Coordination Group (MDCG), see Figure 1. For the COMBINE programme, the CIE and IVD sub-groups of the MDCG are involved in the collaboration in relation to combined studies.

[1] https://health.ec.europa.eu/document/download/77e1409a-f4c0-45db-bff1-4873c7a0e7ae_en?filename=md_combined-analysis-phase-report_0.pdf

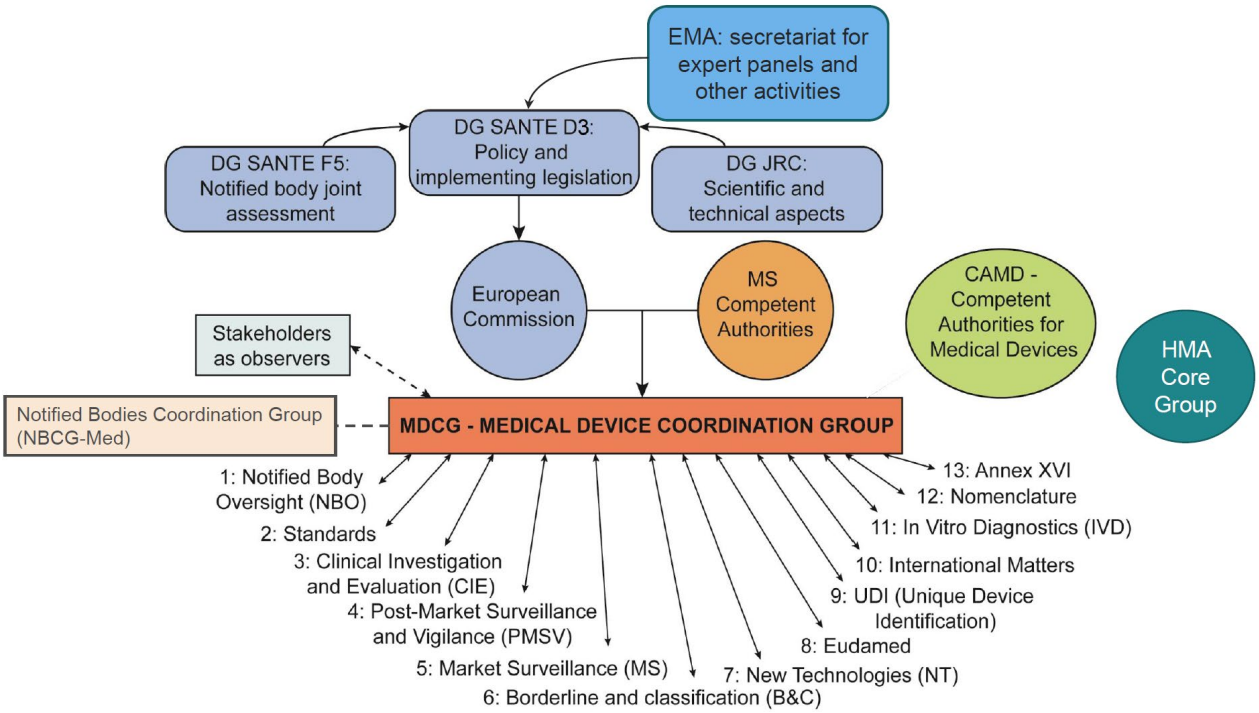

Figure 1: Structure of EU medical devices governance. The MDCG and related expert working groups consists of experts and representatives from the relevant Competent Authorities in the Member States and are hosted by the European Commission.

As outlined in Figure 2, medicines are governed in the EU by the three pillars: The Heads of Medicines Agency (HMA), the EU Commission and the European Medicines Agency (EMA). Within the medicines area, the topic of clinical trial authorisation by national competent authorities (NCAs) is governed by the following two EU groups: CTCG at the HMA and CTAG at the EU Commission as depicted below. The CTCG represents experts closest to the authorisation of clinical trials at Member State level and directly responsible for activities in relation to combined studies. The CTAG brings together national contact points from each Member State in relation to clinical trial authorisation and is responsible for endorsement of documents that need EU Commission oversight as well as the overall COMBINE programme strategy. The EMA contributes with relevant expertise in relation to coordination of authorisation of medicinal products, scientific advice, scientific consultation of companion diagnostics and being responsible for CTIS.

The ethics committees system is made up of national medical research ethics committees (MRECs) for both medicines and devices, sometimes the same committees cover both aspects and sometimes the committees are separate. Ethics committee experts were initially invited to COMBINE through both the former Clinical Trials Expert Groups (CTEG) at the EU Commission and through the MDCG. During the COMBINE analysis phase, the CTEG group has been closed and the MedEthicsEU forum has been established representing Ethics Committees of both medicines and devices in EU and has thus been included as a reference group providing input to the COMBINE programme work and contributing to the work as relevant and support implementation of solutions.

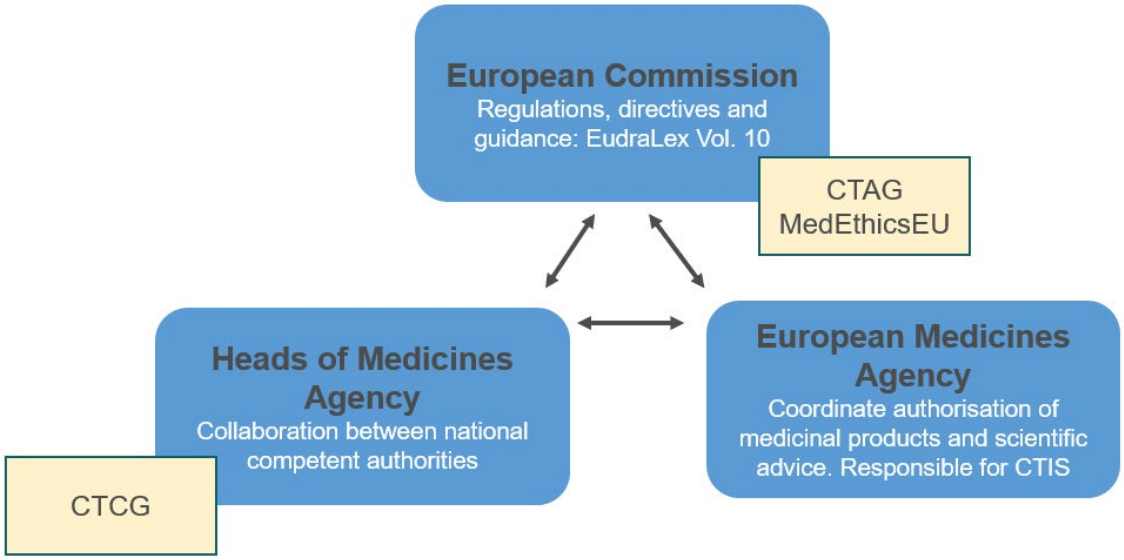

Figure 2: Structure of the EU Medicines Governance relevant to clinical trial authorisation. The clinical trial advisory group (CTAG) and the clinical trial coordination group (CTCG) consists of Member State clinical trial experts from the competent authorities. The MedEthicsEU consists of Member State representatives from the Ethics Committees secretariats of Research Ethics Committees (RECs) and cover both medicines and devices.

5. Structure and governance

The COMBINE programme is a voluntary cooperation mechanism in which the relevant Member State groups and stakeholders can monitor and implement actions of common interest related to combined studies. It is acknowledged that there are already developed governance structures in the medical device field and in the field of medicinal products. In addition to this existing sector-specific framework there is willingness on the part of Member States and stakeholders to make sure that these groups are in contact and continue working together on issues related to combined studies, building on the success of the analysis phase of COMBINE.

To understand how the programme should best be set up, it is important to examine the issues and the actions proposed in the analysis report. While all the issues and actions identified in the analysis phase of COMBINE have cross-sectorial relevance, the way to address them can differ. For instance, one of the issues raised was the lack of clarity on how sponsors can practically approach serious adverse event reporting in combined studies, given that the requirements are not identical in MDR/IVDR and CTR. This is an example of an issue on the interface of the legal frameworks that can only be addressed by joint discussion of relevant actors. Another issue raised was lack of clarity on when a given device study becomes a PS or CI according to the definition in the IVDR or MDR. While the answer clearly impacts combined studies, in contrast to the previous example it is a question specific to the device field and therefore it is appropriate that the relevant device expert group is primarily responsible for developing the answer, with inputs from all relevant actors as needed.

Therefore, the COMBINE programme must fulfil the following complementary purposes:

1) For sector-specific actions whose outcome is relevant for COMBINE, rely on the work in the sector-specific groups while enabling them to add a cross-sectorial perspective as needed.

2) For cross-sectorial actions, serve as the framework in which they can be analysed and solutions developed and implemented with participation of all relevant actors. Facilitate interaction with the sector-specific actions if relevant.

To achieve these, and to build on the positive experience with the way of working of the analysis phase of COMBINE, the COMBINE programme is structured as follows (see also Figure 3).

1. The programme is owned by the relevant Member State groups which were the reference groups for the COMBINE analysis phase: the MDCG, CTAG, CTCG. MedEthicsEU contributes with resources and input and supports implementation as relevant.

2. The existing 'project management' set of COMBINE groups are maintained but elevated to the level of the programme as a whole: the project steering board becomes the programme steering board, the project group becomes the programme group, the stakeholder group becomes the programme stakeholder group, and the project manager becomes the programme manager. The programme manager is supported by the programme office. The purpose of this set of groups is to drive and monitor the programme as a whole.

3. For each action in the programme, one of two modes can be used (see bottom part of Figure 3). For the sector-specific actions with relevance for COMBINE, they should be tackled mainly within the sector-specific groups, i.e.:

    - CT matters with relevance for COMBINE in the CTCG and CTAG;
    - PS/CI matters with relevance for COMBINE in the MDCG and its relevant sub-groups, namely the Clinical Investigation and Evaluation working group (CIE WG) and the In Vitro Diagnostics working group (IVD WG);
    - Ethics matters with relevance to both CT as well as PS/CI in MedEthicsEU as appropriate.

    The sector-specific groups can draw on the programme groups as they see fit to ensure a cross-sectorial perspective, for example they may use the programme group and/or the programme stakeholder group to better understand the underlying issues or obtain input on the suitability of proposed solutions. The outcomes should be endorsed by either the MDCG or the CTAG depending on whether it is a PS/CI or CT-specific issue.

    For the cross-sectorial actions driven by the COMBINE programme, work is organised in projects with dedicated task forces involving participants from any relevant MDCG sub-group, CTCG, CTAG, MedEthicsEU or the EMA. The programme stakeholder group should be used for input to the work of these task forces. The other programme groups (the steering board and the programme group) may be used as needed for strategic advice or broader cross-functional input to projects and outcomes will be endorsed by both the MDCG and the CTAG.

Thus, the COMBINE programme is not intended to replace or significantly change already existing structures. Rather, the intention of COMBINE is to provide a framework for cross-sectorial work in relation to combined studies that cannot be solved by a single sector. The programme will also enable enhanced communication and joint monitoring and evaluation of all actions of common interest, including those carried out in the sector-specific groups together with the cross-sector work carried out in the COMBINE framework.

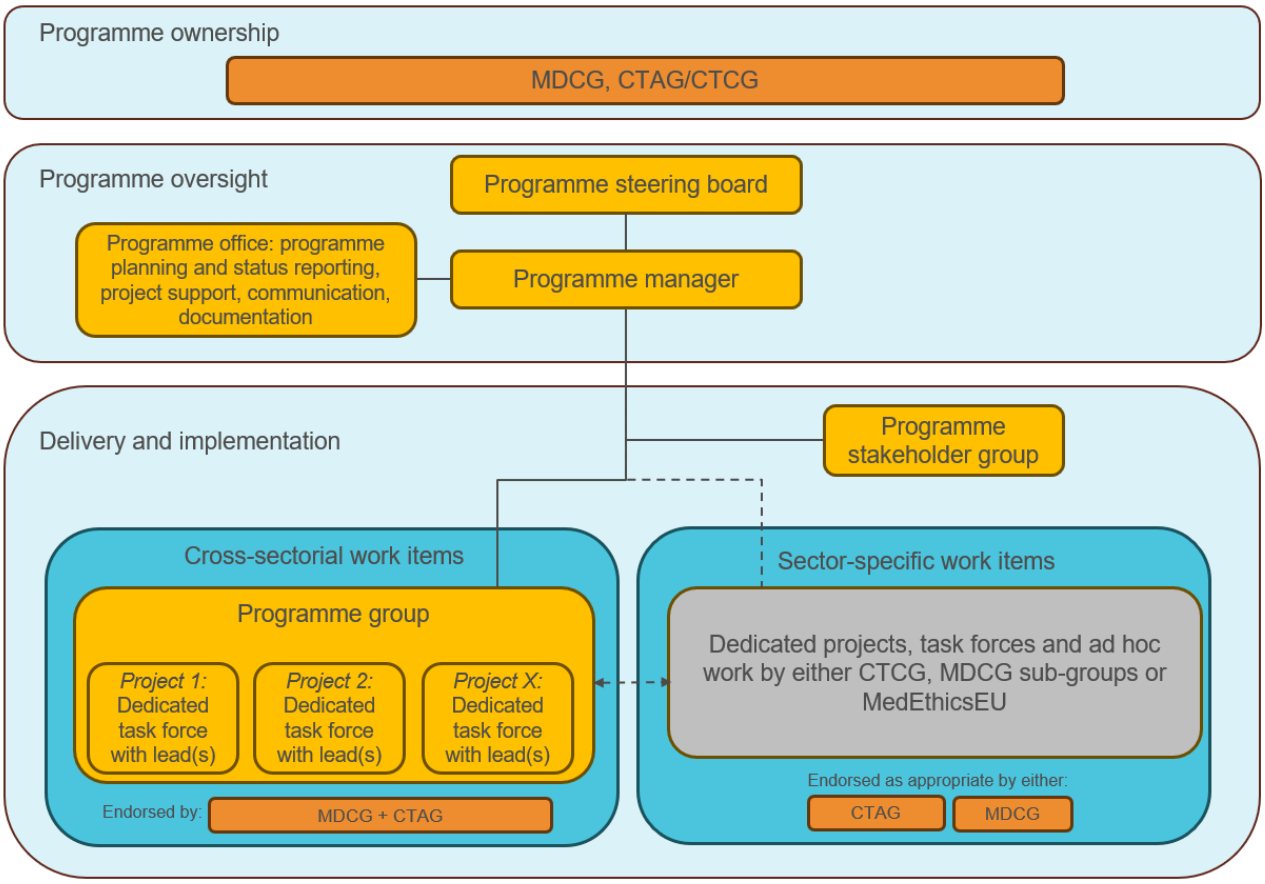

Figure 3 The structure and governance of the COMBINE programme

6. Programme action plan

The programme will progress according to the programme plan shown in Table 1 below with review and further detailing of the programme plan between stages. The actions proposed in the analysis report have been reviewed and consolidated to produce this plan.

It is divided into three thematic areas: (1) **Coordinated assessment**, (2) **Alignment** and (3) **Communication and dialogue**.

Coordinated assessment refers to coordination in the assessment of combined study applications by competent authorities, as well as by ethics committees. There are different levels of coordination, including:

- internal coordination at national level, between different authorities and between ethics committees,
- coordination across Member States in one sector,
- coordination both across the medicinal product and medical device sectors and across Member States.

The thematic area covers different aspects of this coordination including coordinated assessment in the device field as well as the cross-sectorial multinational coordinated assessment.

Alignment refers to aligning the understanding of various concepts and requirements across Member States and sharing information on national requirements.

Communication and dialogue cover various actions on exchange of information, advice and training.

The areas broadly correspond to the COMBINE phase 1 analysis report, with the area named Guidance and clarity merged with the Alignment area. The work has then been organised into projects with task forces (and one smaller task). Each cross-functional project will be further defined prior to start by the groups involved to ensure clarity on scope and deliverables.

In terms of prioritisation, the programme is loosely divided into three stages numbered 1-3. The actions have been assigned into one of the three stages as a function of the urgency of the action and of the available resources. The indicative planning for the stages is outlined below:

- Stage 1: actions already ongoing or indicatively planned to be initiated in 2024 – Q1 2025
- Stage 2: actions indicatively planned to be initiated in Q2 2025 – Q1 2026
- Stage 3: actions indicatively planned to be initiated in Q2 2026 – Q1 2027

Stage 1 will start with a main focus on coordinated assessment. It will also include some cross-sectorial work within Alignment, where many of the sector-specific actions are already ongoing in their respective groups. Stage 2 will focus more on cross-sectorial alignment and initiate work within Communication and Dialogue. Stage 3 will continue with Communication and Dialogue activities.

The stages are intended to serve as means to incorporate opportunities for a general review of the programme in terms of planning as well as ways of working, where the projects of the next stage will be planned in more detail. Some actions will likely be going on across stages, however, enough work should be completed to reflect on progress and take a status on the planning for the next stage. The timeframes for the stages reflect when the work is expected to be initiated. New projects may be added to the action plan as the programme proceeds.

Table 1: Summary of COMBINE programme action plan

Area	#	Topic	Nature	Action	Stage
Coordinated Assessment	1.1	CI/PS CA Voluntary Coordinated Assessment	Sector-specific (CI+PS)	Establish coordinated assessment of CI in the absence of CI/PS module of Eudamed	1
				Establish coordinated assessment of PS in the absence of CI/PS module of Eudamed	2
	1.2	'All in one' coordination assessment - across Member States competent authorities and ethics committees	**Project 1:** Cross-sectorial Taskforce	Analyse possibilities for CT/PS coordinated assessment of clinical trials with an IVD in development as companion diagnostic. Propose outline for procedure including appropriate IT solution for all parties involved and encouragement of dialogue between relevant actors at national level as relevant.	1
				Establish pilot for CT/PS coordinated assessment or clinical trials with an IVD in development as companion diagnostic. Based on learnings, make recommendation for a voluntary procedure for both CT/PS and CT/CI combined trials.	2
		IT Infrastructure		Convey learnings on business procedures from 'all in one' coordination pilot to ongoing work on integration between CTIS and EUDAMED	2
Alignment	2.1	Align Member State positions on questions pertaining to single Regulations	Sector-specific (CI/PS/CT) *- to be mapped to relevant ongoing, delivered or planned work*	Clarify single Regulation questions: I. Performance studies involving testing sites only II. When a PS or CI is needed III. Definition of left-over sample IV. Surgically invasive sample taking V. Transition of combined studies VI. Studies with no benefits for minors	1 and 2
	2.2	Align Member State positions on questions on the interface of MDR/IVDR/CTR	**Project 2:** Cross-sectorial Taskforce	Optimise serious adverse event reporting in combined studies. Discuss and propose solution for clarification of procedures.	1
			Project 3: Cross-sectorial Taskforce	Clarify aligned approach between MDR/IVDR/CTR with proposal for solution on topics relevant to application processes: - Early termination of combined studies - IVDs in a single trial and same IVD in multiple trials - Procedures for substantial changes - Responsibilities of sponsors and manufacturers	2
			Project 4: Cross-sectorial Taskforce	Explore the different modalities of using medical devices and IVDs in clinical trials of medicinal products, in order to clarify what is the applicable regulatory context for those devices and IVDs.	2
	2.3	Develop understanding of national requirements for applications	**Task 7:** Cross-sectorial (COM)	Collate feedback from stakeholders on different Member State practices on documentation and forward to relevant groups for consideration. Encourage Member States to make information available on national requirements that impact combined studies.	1
				Collect and publish a set of links to national websites.	2
Communication & Dialogue	3.1	Scientific/ technical advice and exchange of best practice	**Project 5:** Cross-sectorial Taskforce	Clarify need for advice and assessor fora.	2
				Explore whether existing advice can be expanded with expertise to cover combined studies.	
				Propose establishment of necessary addtional assessor fora.	
	3.2	Training	**Project 6**: Cross-sectorial Taskforce	Clarify need for training and collect existing training or develop sustainable training material accordingly.	3

Figure 4 illustrates the progression in work as a transformation diagram: moving from the current situation towards the one expressed in the vision for the COMBINE programme (see section 3). The COMBINE transformation diagram will be used to follow the status and activities of the COMBINE programme at a high level.

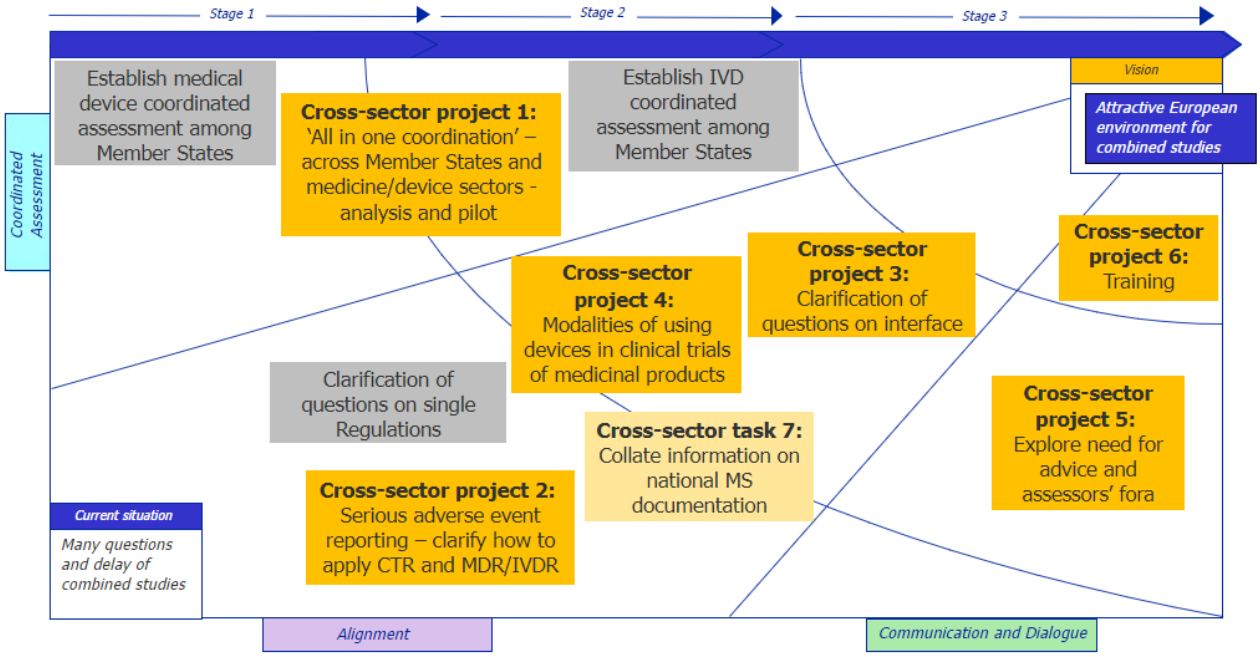

Figure 4 Graphical representation of the actions as a transformation diagram moving from the current situation to the vision of the programme

In principle, the COMBINE programme is expected to end after the work items listed in Table 1 have been completed. It will be reviewed regularly as described above and may therefore be modified, condensed or extended with further stages according to collectively identified needs.

6.1 Summary of proposed COMBINE cross-sector projects

This section provides a summary of each of the cross-sector projects.

Cross-sector project 1: 'All-in-one coordination'

This project is intended to explore coordinating assessments of applications for combined studies among Member States (including competent authorities and ethics committees) and across the CTR and IVDR or MDR. It should focus on clinical trials of a medicinal product combined with a performance study of a companion diagnostic IVD and include an analysis, a pilot and a review of these. In addition, it will convey learnings on IT business procedures for integration between CTIS and EUDAMED. Eligibility criteria for the pilot are expected to be published early 2025. The pilot is expected to run from mid-2025 to mid-2026.

Cross-sector project 2: Serious adverse event reporting across CTR/IVDR/MDR

This project aims to clarify how to apply the CTR, MDR and IVDR requirements on serious adverse event reporting in combined studies, including a comparison of safety reporting procedures under each legal framework, workshop or consultation with stakeholders and clarifications in an appropriate form (e.g. in a guidance document). The project is expected start in early 2025 and expected to run over the full year.

Cross-sector project 3: Questions on authorisation and/or notification-related processes on the interface of CTR, MDR and IVDR

This project aims to clarify questions on aligned application of CTR and MDR or IVDR where joint discussion across sectors is necessary. Examples include relative responsibilities of sponsors and manufacturers of the medicine and device, management of changes to the study, procedures for early termination etc. Questions should be addressed by means of a guidance or similar tool. The project is expected to start in early 2026 and to end in early 2027.

Cross-sector project 4: Modalities of using devices in clinical trials of medicinal products

The purpose of this project is to explore the different modalities of using medical devices and IVDs in clinical trials of medicinal products, in order to clarify what is the applicable regulatory context. Some examples are devices used outside their intended purpose within a clinical trial, devices authorised in a third country, as well as software used in clinical trials. A set of scenarios should be compiled and the applicable regulatory framework clarified. If deemed appropriate, a guidance document or similar tool will be used to capture some or all of the outputs. One possibility is the update and expansion of MDCG 2022-10. This project is expected to start in the first half of 2025 and end in late 2026.

Cross-sector project 5: Explore need for advice and assessors' fora

The purpose of this project is to explore needs and opportunities for advice to sponsors and for exchange of best practice among assessors. Regarding advice to sponsors, the project will include work with stakeholders to clarify sponsor needs for advice, assessment of which elements of those needs are covered by existing mechanisms for advice, and proposals for how gaps could be addressed. An analogous analysis will be conducted for fora for exchange of experience and best practices among competent authorities and/or ethics committees. The project is expected to start in the second half of 2025 and to end in the second half of 2026.

Cross-sector project 6: Training

The purpose of this project is to explore the needs for training for sponsors, competent authorities and ethics committees in the area of combined studies, and collect existing training materials or develop new materials as appropriate. This project is expected to start in early 2027 and end in the second half of 2028.

Cross-sector task 7: Collection of information on national requirements

As part of this project, firstly the European Commission will collate feedback from stakeholders gathered during the COMBINE analysis phase on different Member State practices for documentation requirements for combined study applications, in order to facilitate stock-taking by the Member States. Secondly, Member States will be encouraged to make information about national requirements impacting combined studies easily available to sponsors on their websites. The Commission will collect and publish a set of links to these national websites. This work is expected to start in early 2025 and be completed by the end of the year.

7. Working methods

This section describes the roles and responsibilities of different actors within COMBINE and the programme's working methods.

The MDCG and the CTAG are responsible for endorsing the programme strategy, the action plan as well as the action outcomes. In line with the governance described in section 4, both groups endorse the general programme documents and the outcomes of the cross-sectorial actions, whereas

for the sector-specific actions each group endorses the actions relevant to them. The programme steering board may propose any major questions or issues regarding the COMBINE programme for discussion at the MDCG and/or the CTAG.

The **programme steering board** consists of the Member State expert group chairs and European Commission representatives working with the involved European expert groups, together with the programme manager facilitating the collaboration. The board is responsible for providing strategic direction and support to the activities in relation to COMBINE by facilitating resolution of major issues and generally paving the way for the COMBINE activities in the network. The board is responsible for maintaining the programme plan and strategy with support from the programme office and manager. The board should meet on a regular basis and may also participate in the meetings of the programme group and/or the stakeholder group when appropriate. The programme board chairs from the European Commission facilitate interaction with the endorsing groups (MDCG, CTAG), are overall accountable for paving the way for the activities under COMBINE and are the primary support for the programme manager.

The **programme group** consists of experts across the regulatory and ethical committee network that have broad knowledge and interest in the activities in COMBINE. They will often be experts taking part in some of the ongoing work in COMBINE or be senior experts wishing to contribute with knowledge and experience. The programme group will bring a cross-functional overview of and input to COMBINE activities from an operational and scientific perspective and broad support for implementation of deliverables as they constitute an important link to the expert groups. The programme group should meet several times a year to follow the progress of the COMBINE action plan, provide relevant cross-sector input and take stock of the objectives and key results (see section 7) with feedback relayed to the steering board. The programme group may meet on its own or with the participation of the stakeholder group.

The **stakeholder group** consists of representatives from relevant EU associations that contribute with input from their members and thus ensure external stakeholders' input to the COMBINE activities. The membership of the stakeholder group is open to representatives of European or international associations with practical experience in the EU in the field of combined studies around applying for, setting up, participating in or conducting combined studies so they may contribute input effectively on behalf of their association. Each association has approximately two members in the group who are responsible for dispersing information and collecting input and feedback from their member organisations.

The **programme manager** is responsible for facilitating the collaboration and dialogue across the COMBINE programme and chairs the board, programme group and stakeholder meetings. The programme manager supports the board on programme strategy, ensures the overview on planning with support from the programme office and is responsible for ensuring relevant support to the task forces conducting the project work.

The **programme office** supports the programme board and manager and are responsible for the operational and planning aspects of COMBINE as agreed with the board and programme manager. The programme office will be staffed by voluntary contribution of experts from Member States and can work can be divided into the following roles:

- Programme planning and status on issues resolution and OKR measurements also ensuring alignment of issues resolution with the relevant sector-specific and cross-sectorial work.

- Project management support to task forces in relation to project planning and facilitation of project tools as agreed with task force leads.
- Administrative support such as meeting minutes, maintaining decision log, ensuring proper structure and archiving of documents on Sharepoint site and coordinate meetings.
- Communication and change management ensuring all parties internally and externally are timely informed and change management activities are incorporated into project plans.

The **task forces** are responsible for conducting and delivering work in line with the pre-agreed scope, with the organisation ensured by the task force leads with support from the programme office and programme manager.

As regards the cross-sectorial actions, **Member State leads** must be identified prior to starting the work in the upcoming stage (i.e. before stages 1, 2 and 3 referred to above). Ideally these actions should be co-led by representatives from each relevant sector. The leads should request volunteers from any relevant MDCG sub-group, CTCG, CTAG or MedEthicsEU, ensuring a cross-sectorial representation appropriate to the nature of the action. The leads are responsible for organising and facilitating the work of the task force with support from the programme office project support or programme manager as relevant. The leads should consult the programme group, the stakeholder group and the steering board of COMBINE during the development of the deliverable.

For the sector-specific actions the usual methods of the main responsible working group should be used. The leads may request the programme group and/or the stakeholder group of COMBINE to provide input at any stage of the implementation they consider appropriate, for example in the beginning to better scope the issue at stake or towards the end to consult them on the proposed solution.

For both sector-specific and cross-sectorial actions, the leads may be requested to inform the programme group, stakeholder group and the programme office of the progress with their action.

8. Evaluation of programme activities

It is clear that the combined study ecosystem is very complex. The efficiency of such studies and the attractiveness of the EU as a region to perform them depends on many factors. The COMBINE programme seeks to improve the clarity and efficiency of the regulatory system for authorisation of the studies, which is one element of this ecosystem.

Despite this complexity, evaluation of progress is a key element of any programme and it is essential to reflect on how the success of COMBINE can be evaluated. For this purpose, a set of objectives and key results will be developed to follow the progress of the programme considering the COMBINE vision. These will be regularly reviewed by the programme group and steering board.

The COMBINE programme is committed to involve all relevant parties in a collaborative and active way to address practical needs, facilitate the application of European legislation and strive to meet the COMBINE vision, with the ultimate goal to support availability of innovative treatments for EU patients.