btrust

# MANUAL for a CO-CREATION PROGRAMME

Policy version:

Inclusive approach to a risk-benefit assessment to guide regulatory frameworks and decisions for new innovations

# A co-creation programme for meaningful stakeholder involvement

## To give directions to the development, regulation and implementation of new technologies

Innovations like new technologies can be disruptive and have a whole range of consequences, negative (risks) as well as positive (benefits), or neutral changes. They can change the world in ways that are sometimes hard to predict, but especially negative consequences must be anticipated and mitigated as much as possible.

The development, implementation and regulation of new technologies, including a broad assessment of the consequences, thus needs an inclusive process that involves all relevant stakeholders – ranging from those responsible for regulation, production and implementation as well as those expected to make use of the results and those speaking for the effects on environment or social structures.

This inclusive approach has taken the form of a co-creation programme, and can enable policy makers, researchers and industries to make legislative and application-oriented choices that are relevant, feasible and acceptable for the majority of those involved.

Its main objectives are to pinpoint the hurdles and cues for acceptance and uptake, and find solutions with regulatory interventions, communication strategies, targeted financing of research, practical developments and guidelines, conditions for implementation, etc.

## CO-CREATION PROGRAMME IN FOUR PHASES

### 1. Explore

- ✖ Map consequences and alternatives
- ✖ Map stakeholders
- ✖ Evaluate consequences per stakeholder

### 2. Involve

- ✖ Prioritise stakeholders for involvement
- ✖ Involvement strategy
- ✖ Roll-out

### 3. Assess

- ✖ Identify hurdles, cues & potential
- ✖ Validate
- ✖ Prioritise

### 4. Co-design

- ✖ Find solutions, improvements & mitigation strategies
- ✖ Validate

© 2024 B-TRUST Project.
This document is available under the terms of the Horizon Europe Grant Agreement No. 101134847. Reproduction is authorised provided the source is acknowledged.

# Toolbox added to the manual

The manual describes the different steps in more detail and indicates what results to expect in each step. It also highlights the key points for each step, as well as tips and tricks for each step. Accompanied with the manual you can also find a toolbox, which contains more practical tools and step-by-step walkthroughs of certain parts of the programme.

**The toolbox contains:**

## 1. Explore

## 2. Involve

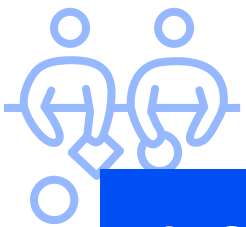
Consequences mapping tool

Stakeholder mapping tool

Co-creation toolbox

Communication & recruitment toolbox

## 3. Assess



## 4. Co-design

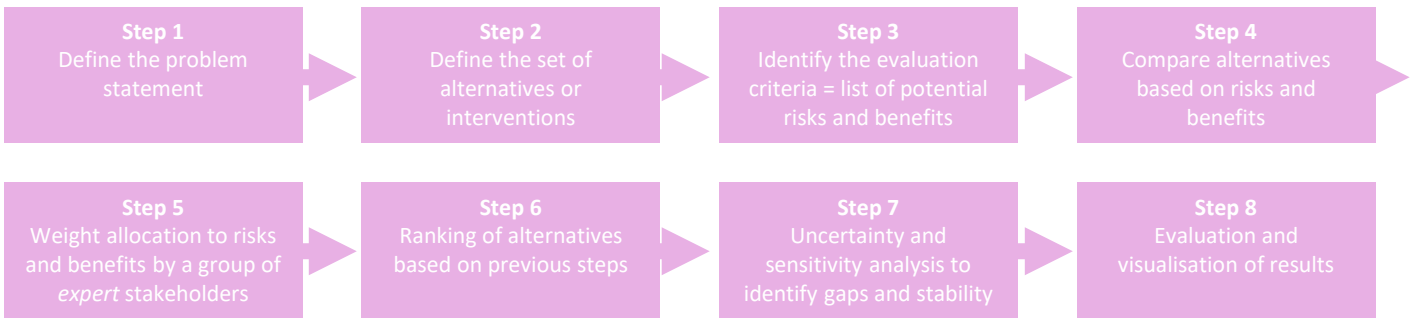
Co-design toolbox

# Inclusive approach to a risk-benefit assessment to guide regulatory frameworks and decisions for new innovations

This application of the programme concerns the regulation of new innovations (or technologies). In this context, it provides an approach for gathering additional input from stakeholders in a participatory manner, to support a multi-criteria decision analysis (MCDA).

The MCDA is a structured framework that is often used to guide regulatory decisions, as it provides guidance on weighing the risks versus the benefits of a new situation (or a set of situations) against a predefined reference. In a food, health and safety context, it is a proven method to assess new and changing situations, like new ingredients and new technologies. This because it provides outcomes that are evidence-based, reproducible, and well-documented.

An overview of the steps of the MCDA procedure is given below.




The first steps of the MCDA procedure partly aligns with the first phase of the programme, as the consequences mapping procedure is based on the risk-benefit analysis of the MCDA. Whereas the programme then focuses on gathering input from multiple viewpoints, while the original MCDA procedure primarily relies on expert input. A multi-stakeholder approach for gathering additional input is mentioned, but there is no guidance on a concrete approach. This is however, where the programme steps in and provides guidance on mapping the stakeholder ecosystem, setting up an engagement strategy, and interpretation and validation of the results.

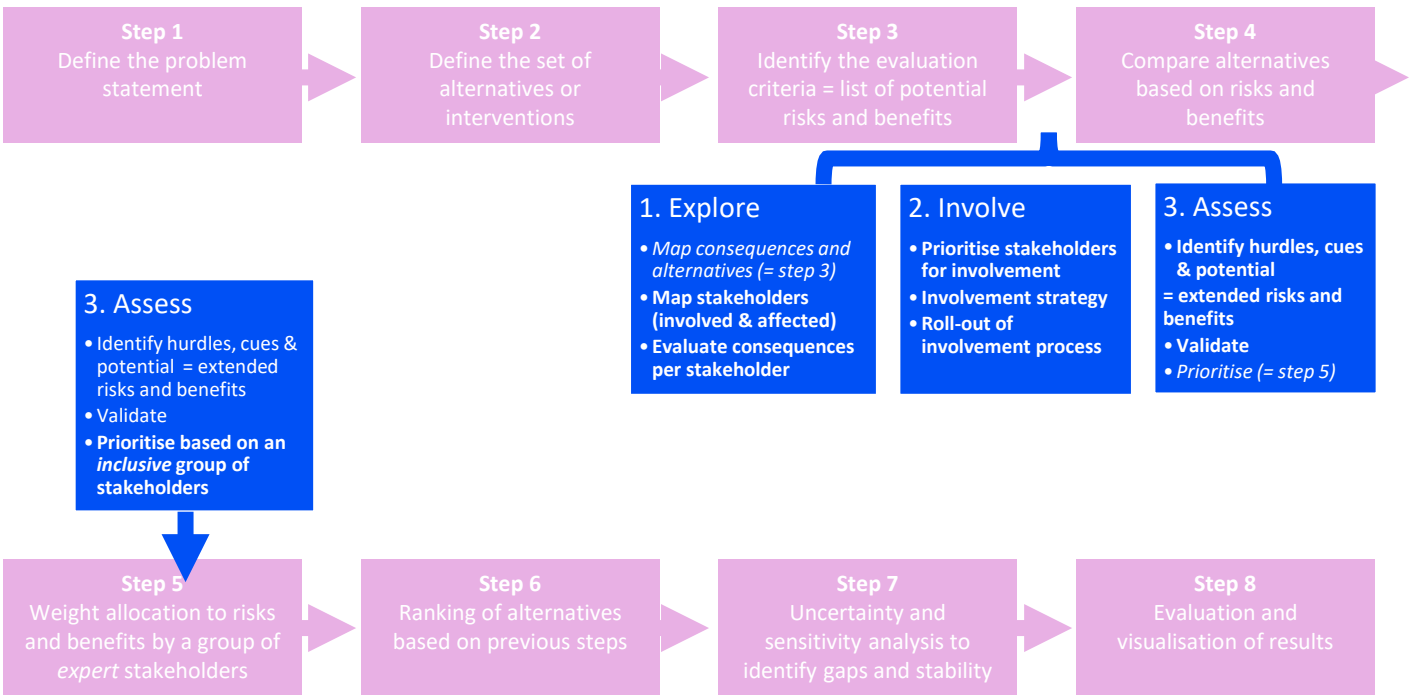
The programme does not continue with the assignment of weights to individual risks and benefits, but does allow the use of multiperspective data to include in the actual assessment, for which the MCDA provides a well-elaborated procedure.

## Expected outcomes

- ✖ A clearer view on how different stakeholders are affected by the risks and benefits of the innovation or technology
- ✖ An extended list of risks and benefits, including how their importance is perceived by different stakeholders and how adequate mitigation strategies are perceived, based on input from the stakeholders themselves

# Inclusive approach to a risk-benefit assessment to guide regulatory frameworks and decisions for new innovations

The following figure shows how the process from the MCDA (in pink) and the B-Trust co-creation programme (in blue) fit together.




The description of the procedure in this manual is focused on the parts that either overlap with or are exclusive to the programme. For a detailed guidance on the full MCDA procedure, we refer to Tool #62 from the Better Regulation Toolbox set out by the EC (2025).

## Main pitfalls and attention points

- ✖ Open-mindedness: As an expert, it can be hard to think beyond the current (legal and subsidy) systems in place, and even beyond cultural habits. Involve partners that are experienced in differential thinking.
- ✖ Openness and flexibility: When stakeholders are engaged to guide regulatory decisions, there must be sufficient openness and possibility to include their input in the resulting decisions.
- ✖ Access to stakeholders: Many stakeholder groups are not part of the policy makers' usual network, and engaging a diverse and representative sample may prove difficult. Collaborate or contract networks and partners that have sufficient access to these stakeholder groups.

# The pre-phase

**Step 1**
Define the problem statement

**Step 2**
Define the set of alternatives or interventions

Before launching the trajectory of the programme, the organising team should confirm five things:

## Case
Formulation of the decision problem: What technology or innovation is under revision for creation or application of a regulatory framework?

## Room for influence
What can still change as a result of the trajectory, and what is already fixed?

## Ownership
Who is responsible for organising the trajectory, synthesising the results, and converting them into action?

## Central question
How are risks and benefits balanced against a defined reference situation?

## Decision context
How will the results be incorporated in the regulatory framework?

The concrete output of this start-up step is a case brief, an agreed trajectory objective, and a named owner for follow-up.

# 1. Explore

**Step 3**
Identify the evaluation criteria

## 1.1 Mapping consequences & alternatives

**What to map:**

✖ Consequences of the innovation / technology in different scenario's for implementation

- POSITIVE Consequences (benefits)
- NEGATIVE Consequences (risks)
- NEUTRAL Consequences (changes)

✖ Different dimensions

- Effects on safety for health, environment and sustainability
- Socio-economic effects
- Direct and indirect effects
- Short-term and long-term effects

**How to map?**

Consequences mapping tool

**Compare**

- IMPLEMENTATION of the innovation (different scenarios)
- NO IMPLEMENTATION of the innovation (original)
- ALTERNATIVE SOLUTION(S)

**Note**

The procedure for this consequences mapping was based on the procedure described for the MCDA itself, they are thus highly aligned. The toolbox gives clear guidance on how to put the process into practice.

**Result**

✖ The different types of effects of implementation in different scenario's: positive, negative and neutral effects, mapped against a defined reference situation

# 1. Explore

## 1.2 Mapping stakeholders and their influence

### Initial mapping from the quintuple helix (5H)

**Who to consider:**

Start from the quintuple helix, and consider for each category:

- ✖ Stakeholders targeted (potential users and beneficiaries)
- ✖ Stakeholders indirectly or unintentionally affected
- ✖ Stakeholders that are responsible for implementation
- ✖ Stakeholders that could influence adoption

### Mapping and evaluating INFLUENCE of the stakeholders

**Aspects of influence to discuss:**

**POSITIVE Influence (push)**

**NEGATIVE influence (set back)**

**Influence on each other**

**Evaluate:** **Degree of influence** (1-5)

**How to map & evaluate?**

Stakeholder mapping tool

### Tips & tricks

- ✖ Most stakeholder mappings also focus on interest of the group. In this context, interest is not a crucial dimension but is part of the 'influence' dimension. Consider this 'interest' aspect when evaluating the degree of influence.
- ✖ Include external parties (preferably linked to the different categories in the 5H) in this exercise to get multiple perspectives, and a more complete view on who your stakeholders are.

### Result

- ✖ An overview of the stakeholders involved, targeted and unintentionally affected
- ✖ The level and type of influence they have on the adoption of the technology / innovation

# 1. Explore

## 1.3 Evaluation of consequences per stakeholder

### Analysis and matching with the consequences mapping

**Stakeholder list** ← **Consequences list**

### Evaluating the AFFECT of the stakeholders

| **POSITIVELY Affected (benefits)** | **NEGATIVELY Affected (risks)** |
|---|---|
| **Degree of benefit** (1-5) | **Degree of risk** (1-5) |

**How to map & evaluate?**

Stakeholder mapping tool

**Attention point**

At this point, there are no weights attributed to each individual risk or benefit. Since the objective of this exercise is pinpointing the most crucial stakeholders for engagement, a rough estimate is sufficient. This estimate can be based on the amount of different risks for the stakeholder, and an estimate of the importance of these risks. Attribution of weights follows later in the process, when the information is more complete.

**Tip**

Not every stakeholder needs the whole process, some stakeholders can be eliminated early on when relation to the innovation is neutral and of little influence.

**Result**

- ✖ The (expected) effect of implementation of the technology / innovation on different stakeholders

# 2. Involve

## 2.1 Prioritise stakeholders for engagement

### Who to engage?

**Prioritisation based on:**

- **Degree of risk** (1-5)
- **Degree of benefit** (1-5)
- **Degree of influence** (1-5)

**Enabling prioritisation:**

**Prioritise:**
1. **High risk**
2. **High benefit**

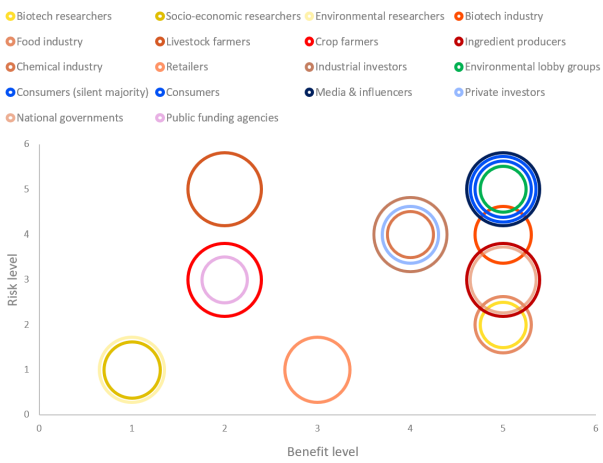
### How to prioritise?

Stakeholder mapping tool

### With calculation

| Stakeholder | Benefits | Risks | Influence | B+R | B+R+I |
|---|---|---|---|---|---|
| Environmental researchers | 1 | 1 | 4 | 2 | 6 |
| Biotech industry | 5 | 4 | 3 | 9 | 12 |
| Food industry | 5 | 2 | 3 | 7 | 10 |
| Livestock farmers | 2 | 5 | 5 | 7 | 12 |
| Crop farmers | 2 | 3 | 5 | 5 | 10 |
| Ingredient producers | 5 | 3 | 5 | 8 | 13 |
| Chemical industry | 4 | 4 | 2 | 8 | 10 |
| Retailers | 3 | 1 | 4 | 4 | 8 |
| Industrial investors | 4 | 4 | 5 | 8 | 13 |
| Environmental lobby groups | 5 | 5 | 2 | 10 | 12 |
| Consumers | 5 | 5 | 4 | 10 | 14 |
| Media & influencers | 5 | 5 | 5 | 10 | 15 |
| Private investors | 4 | 4 | 3 | 8 | 11 |
| EU government | 5 | 3 | 5 | 8 | 13 |
| Public funding agencies | 2 | 3 | 2 | 5 | 7 |

### Visually




### Attention point

The stakeholders identified as most crucial for engagement may be hard to reach and engage.

### Tip

Include external expertise or channels to reach the intended stakeholders.

### Result

- ✖ An overview of how and to what degree stakeholders are affected
- ✖ A priority list of stakeholders most relevant for engagement

# 2. Involve

## 2.2 Set up involvement strategy

### How to engage?

In this phase, stakeholders are best engaged separately, as each group may require a different approach and communication strategy.

### Mode of interaction

**Mode of interaction is dependent on:**

- ✖ The size and diversity of the stakeholder group
- ✖ Personal opinion versus professional stance
- ✖ Time and budget available
- ✖ Competition dynamics between members of the stakeholder group

| Mode of interaction | Best used when | Attention points |
|---|---|---|
| **Small group sessions:**<br>• **Co-creation sessions**<br>• **Focus groups**<br>• **Discussion groups** | • Participants are free to state personal opinions.<br>• A constructive dialogue and discussion are possible, i.e. there is no competition between participants or their mutual challenges are bigger than competition effects.<br>• The stakeholder is large and diverse, with many differences in backgrounds and opinions. | • Different and relevant profiles are present in a well-balanced group.<br>• Ensure that everybody's voice is heard.<br>• Create a comfortable and safe environment that ensures honest feedback.<br>• The goal is to listen and capture different opinions, not convince. |
| **One-on-one interactions (in-depth interviews)** | • Participants speak from an official point of view, as representatives for an organisation.<br>• Certain personalities are hard to engage in constructive dialogue (not respecting of others' opinions).<br>• Competition and confidentiality issues between participants may hinder openness. | • These stakeholders have potentially high impact on the perception of consumers/society.<br>• The goal is to listen, not discuss.<br>• Pay attention to framing and expectation management. |
| **Online input:**<br>• **Quantitative surveys**<br>• **Open calls** | • The stakeholder is large and diverse, and has many differences in backgrounds and opinions.<br>• There is limited budget for physical interactions. | • Target group (input providers)may not be sufficiently large, representative or diverse.<br>• Use non-steering formulation of questions (surveys). |

# 2. Involve

## 2.2 Set up involvement strategy

## How to engage the right persons?

### Profiling & recruitment

How you approach your recruitment (targeted versus untargeted) has a great influence on the profiles that participate in interactions.

| | Pros | Cons |
|---|---|---|
| **Open call (untargeted)** | • Unlimited input<br>• Non-discriminating | • Large self-selection bias<br>• Missing out on hard to reach voices |
| **Closed invitations (targeted)** | • Representation of population<br>• Also targets hard to reach voices | • Not everyone is invited<br>• Might be difficult to engage targeted groups |

**Profiles to consider within stakeholder groups, proportional to the composition of the group:**

- ✖ Age, gender and cultural diversity
- ✖ Various educational backgrounds (scientific & technological literacy)
- ✖ Openness towards new innovations and technologies

**How to communicate & recruit?**

Communication & recruitment toolbox

### Tip

There might be many important stakeholders that are necessary to involve: a good strategy is crucial to make sure the different stakeholders are involved in the correct way. It might be useful to make use of external guidance to come to an effective strategy, and involve external parties with access to the stakeholder groups, a neutral position and a critical eye.

### Attention points

- ✖ Objectivity needs to be safeguarded.
- ✖ In this phase it is not advised to mix stakeholder groups.
- ✖ Outline the power the stakeholders have in the engagement process in order to manage expectations correctly.

### Result

- ✖ A strategy for involving each stakeholder group:
  - Who should be involved
  - How should they be involved

# 2. Involve

## 2.3 Roll-out involvement process

### Setting up the central questions

1. What is your general perception of the technology (innovation) and the specific case?
2. What is the potential (direct and indirect) impact of the technology (innovation), both in general and on you specifically? Positive (benefits) / Negative (risks) / Neutral (changes)
3. What are alternative ways to solve the same problem, and how do the risks and benefits compare?
4. Are the proposed mitigation measures adequate? Are there conditions that need to be met to address concerns?

### Setting up the sessions

Ideal group size:
8-15 participants.

**The setup decides the reliability of answers:**

- ✖ Indirect questioning and exercises
- ✖ Contextualisation: make concepts as 'tangible' as possible with examples, demonstration materials, real-world applications, …
- ✖ Stepwise approach

**Your communication approach during the session influences input:**

- ✖ Use layman's terms to make sure everyone understands what is being discussed.
- ✖ Focus on 'why?'.
- ✖ Be as neutral as possible

**Setting up flow and exercises?**

Co-creation toolbox

### Timeline

A streamlined process for a co-creation session should take about 6-8 weeks. Participants need to be invited 4-8 weeks prior to the session.

### Attention points

- ✖ Those easiest to engage are not necessarily the most relevant.
- ✖ Avoid common biases and factors interfering with openness, such as peer pressure or politeness answers, judgement or intimidation through your set-up.

### Tips & tricks

- ✖ A relaxed atmosphere supports honest input.
- ✖ Serve food and drinks for a welcoming environment.

### Result

- ✖ Outcomes of the interactions with each stakeholder group

# 3. Assess

## 3.1 Identify hurdles & cues

| Analysis | |
|---|---|
| **Qualitative** | Coding and clustering<br>List recurrent themes and ideas<br>No quantification |
| **Quantitative** | Statistical analysis<br>Clustering of open answers<br>Correct for representativeness of the population |

### Hurdles

- ✖ Risk factors, negative consequences or unwanted side effects, including indirect & socio-economic effects
- ✖ Bottlenecks, loopholes & counterproductive effects
- ✖ Negative perceptions and associations

### Cues

Elements that could overcome the hurdles:

- ✖ Trade-offs
- ✖ Conditions for acceptance
- ✖ Positive perceptions and associations
- ✖ Solutions and mitigation strategies for hurdles

### Attention points

- ✖ The group is optimized to represent maximum diversity, but is not representative for your population.
- ✖ Do not attempt to quantify the data, even though it is tempting to do so. Clear (quantitative) tendencies should be interpreted as an indication that needs to be validated quantitatively, not as facts.
- ✖ Analysis of qualitative data is prone to bias: Be vigilant of your own opinions and biases, and do not to let them interfere with the analysis.
- ✖ Consider the implications and limitations of your set-up (see also in co-creation toolbox).

### Tips & tricks

- ✖ Let at least two people analyse the data, and use AI as external validation.
- ✖ AI can support clustering and identification of recurring themes, but should never be the sole analysis tool.
- ✖ There is more data than what is being said, written or drawn:
  - Things not being said
  - The way things were said
  - Facial expressions, physical behaviour and body language.

### Result

- ✖ A list of hurdles that could hinder the uptake and success of your innovation, and cues that could form the basis of implementation and communication strategies to overcome them
- ✖ Potential alternative applications or positionings for your innovation

# 3. Assess

**Step 4**
Compare alternatives based on risks and benefits

**Step 5**
Weight allocation to risks and benefits by a group of *expert* stakeholders

## 3.2 Validate hurdles & Prioritise

**Validation is essential to verify the data from the assess phase, which is based on qualitative data and cannot be quantified**

### Validate with:

- ✖ New surveys can validate the qualitative findings and allow for quantification (how important or certain risks or benefits to the users?).
- ✖ Results from previous research

### Prioritise:

- ✖ Use the data from the quantification as input for the attribution of weights
- ✖ Which risks and benefits should be taken up further in the assessment?
- ✖ Which risks could be better mitigated with follow-up research?

### Attention points

- ✖ A literature search can provide information on similar research, but can be outdated or give different results due to cultural differences or slight nuances in the case.
- ✖ The target group needs to be relevant and representative.
- ✖ Keep in mind there is are significant biases in surveys.

### Tips & tricks

- ✖ There are plenty of market research companies with access to large pools of consumers with a diversity of profiles, who can also provide support in the set-up of surveys.
- ✖ For validation with other stakeholders than consumers, such as farmers and industry, collaborate with clusters and representative organisation to collect sufficient data.
- ✖ Open-ended questions give better information on spontaneous thoughts and priorities than closed questions, and are now easy to process with AI.

### Result

- ✖ Validated and quantified results
- ✖ Most important hurdles and cues (with the most potential impact)

# Assessment of risks & benefits

| Step 6 | Step 7 | Step 8 |
| --- | --- | --- |
| Ranking of alternatives based on previous steps | Uncertainty and sensitivity analysis to identify gaps and stability | Evaluation and visualisation of results |

The Co-design phase is in this context redundant, and the process continues with the actual assessment of risks & benefits.

For full guidance on this process, we refer to steps 6-8 of the MCDA procedure.

# Translation into regulatory framework

For further translation into the regulatory framework, the proposed framework should also be challenged by other stakeholders, as outlined in the better regulation guideline and toolbox.

The practical execution of these stakeholder engagements can be supported by the guidance toolboxes for co-creation and co-design, as well as the communication & recruitment toolbox.

**Setting up flow and exercises?**

Co-creation toolbox

**Setting up co-design sessions?**

Co-design toolbox

**How to communicate & recruit?**

Communication & recruitment toolbox

Funded by
the European Union

© 2024 B-TRUST Project.
This document is available under the terms of the Horizon Europe Grant Agreement No. 101134847. Reproduction is authorised provided the source is acknowledged.