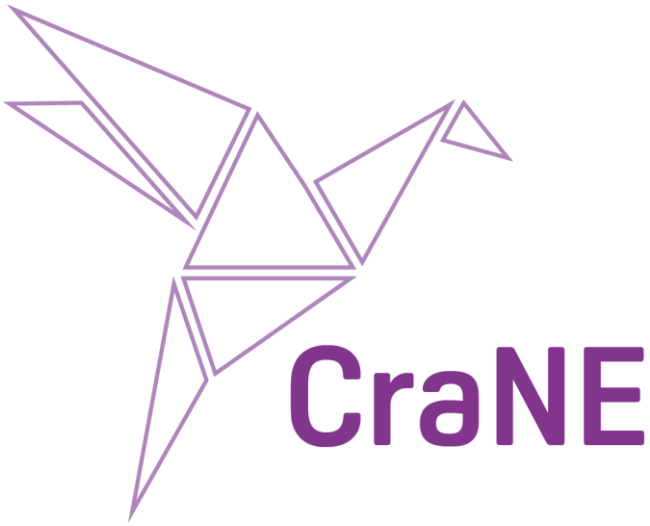

GOVERNMENTAL BOARD

WORKING MINUTES

Brussels, Sciensano
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CRANE

NETWORK OF COMPREHENSIVE CANCER CENTRES: PREPARATORY ACTIVITIES ON CREATION OF NATIONAL COMPREHENSIVE CANCER CENTRES AND EU NETWORKING

Agenda

The first Governmental Board (GB) of the CraNE Joint Action (JA) has been held in person on the 20th April 2023 with a possibility to access remotely via Webex.
CraNE GB began with a welcome by Tit Albreht (NIJZ) Project Scientific Coordinator along with Sciensano (WP4). Presentation of GB functioning, objective and schedule was presented by Sciensano and continued with a short reports and presentations of objectives and expected outputs presented by WP leaders. Short Q&A sessions were held at the end of each presentation. In the afternoon a presentation of synergies and overlaps among EBCP care-related project was delivered by Sciensano followed by a talk by the European Commission on the Opportunities for EC support to EU CCIs network, it revolved by a tour de table of the present MS and a discussion in-person.

Participants

- In-real-life (18): **José Dinis** (Portugal), **Nikolai Goncharenko** (Luxembourg); **Kristiina Ojamaa** (Estonia), **Sascha Reiff** (Malta), Tit Altbrecht (Slovenia), Dorota Dudek-Godeau (Poland), *Sweden*: Annika Baan, Patrik Rossi, Rasul Mirzoev; *Norway:* **Per Magnus Maehle,** Simon Oberst (OECI); *Germany:* **Nele Grapentin** (DKG), Ellen Griesshammer (DKG); *Belgium (Sciensano*): **Marc Van Den Bulcke**, Régine Kiasuwa Mbengi, Hélène Antoine-Poirel, Léopold Vandervliet, Noemie Defourny.

- Virtual (39)*:* Agne Kairaityte (Lithuania), Amélie Gaignaux (Luxembourg), Edit Marosi (Hungary), Kay Duggan-Walls (EC), Lidia Dyndor (Poland), Cristina (Directorate-General of Health Portugal), Zsuzsanna Magyar (OOI, Hungary), Elisa Balducci (Belgium), Witold Szumowski, Wolfgang Seebacher (Austria), **Amanda Psyrri** (Greece), **Ľuboš Drgoňa** (Slovakia), **Eoin Dornan** (Ireland), Sagita Liutkauskiene (Lithuania), Prof Iglika Mihaylova (Poland), Ivana Andrijašević (CIPH, Croatia), Souhade Tabakkalt (Sciensano).
  France: **Jean-Philippe Metges,** Thomas Dubois (INCA)
  Germany: **Karen Budewig** (MoH/BMG), Selamawit Woldai (MoH)
  Italy: Valentina Trapani, E.Vesperini (MoH)
  Slovenia: **Andraž Jakelj**, Karmen Hibrar
  Spain: Rocío Fernández (MoH), Josep M Borras, Andreu Albiach
  Sweden: **David Ylitalo**, Katarina Fredriksson, Nela Lalouni
  Romania: Adrian Brîndusan (IOCN), Delia Nicoara, Alexandra Haiduc (IOCN) [1]

- EC & others: Antonella Canalis (HaDEA), Shawn Baldacchino (JRC-ISPRA), Matthias Schuppe (DG SANTE), Alina Garofil (SANTE-EXT), Jan-willem Van De Loo

[1] Names in bold = Country representatives

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1. Welcome from the CraNE coordination team (Tit Albreht, NIJZ)

Objective of the day: *Discuss the role and functioning of the GB, the expectations, brief about the core WPs (5-8), format and content of main WP4 outputs (i.e. the maturity model and the blue print for sustainability)*

The main aim of CraNE JA is to create an EU Network of the already existing and newly established Comprehensive Cancer Centres (CCCs) to support the implementation of quality-assured early detection, Screening, Diagnosis & Treatment Support to cancer survivors, and Research & Training of the cancer workforce. CraNE JA will help deliver higher-quality care and contribute to reducing inequalities across the EU, while enabling patients to benefit from diagnosis and treatment close to home. This JA will develop a sound model of the EU Network of CCCs including a professional, scientific, educational and administrative framework for a sustainable structure.

The target groups are the main actors who will be concerned in the future development of the EU Network of CCCs: Representatives of Member States, Networks of CCCs, European organisations, Patients, Experts.

CraNE JA brings together 44 partners: 25 Competent authorities and 19 Affiliated entities from 25 different countries

Additional information and some points of discussion:

- Clear mandate (EBCP flagship 5): establishment of the network by 2025 and ensuring access to 90% of the eligible patients to the centres by 2030
- A clear organisational preference
- Earlier consensual definition of a Comprehensive Cancer Care Network (CCCN)
- Development of an inclusive definition of a Comprehensive Cancer Centre (CCC)
- Strengthening the concept of CCCNs, where appropriate, while following its definition from JA CanCon (www.cancercontrol.eu) and JA iPAAC (https://www.ipaac.eu/)
- The EU Network of CCCs as a dynamic, open and inclusive organisation
- Ensuring the loop between care, research, development, training and innovation
- Clear differences in the organisation of healthcare structures in different MS
- More centralised solutions versus more decentralised organisational options
- The focus on access and/or high quality care
- Physical access might be inferior to the demand for high quality and organisational restrictions -> e.g. PET scans, proton therapy

2. WP6 presentation: Objectives and expected outputs (Ellen Griesshammer, DKG)

The objective is to continue the work that has been done in CANCON and iPAAC, and to further develop the access and availability of comprehensive high quality of care in Comprehensive Cancer Care Networks (CCCN) to all Member States (MS) and align the high standards in cancer

care for all quality assured institutions with a focus on the interfaces between care and research (CCCN and CCC).
The CCCNs tools that have been developed during JA iPAAC will be further developed and the tumour specific approach and implementing it in practice will be continued on the example of lung cancer as well as a strong focus on patient-centredness (patient pathway) and development of training concept and supporting instruments for helping MS setting up CCCNs.

Question(s) & Answer(s):
Q1: Where are we through the interface between CCC(s) and CCCNs?
A: The WP6 closely follows the development of the WP7 and will work on the interface/link between both concepts in collaboration with the WP7.

Q2: Lung cancer is a challenge and an opportunity. How do you assure that care pathway could benefit from the development in research?
A: In the WP, we will use the molecular tumour board as an example to show how coordination and connection between tumour-specific CCCNs and CCC should work and to illustrate how such a network could look like.

Q3: Through the development of a structure for the management, could we envision cross collaboration across tumour specific pathway and indications? Are you thinking about making such a connection? Are these discussions held in this WP?
In Norway, we don't have any tumour specific management board, diagnostic tumour boards are based on molecular and genetic analysis and not linked to specific diagnosis.
This will need to be taken into account for specific pathway development, which would not be tumour specific. Linking different tumour management boards across entities need to be taken into account in the discussion of CCCs and CCCNs.

A3: A potential link with the JA JANE that deals with networks of expertise could be a great entry point to create contacts as well as the generic CCCN set of standards that was developed in iPAAC.

3. WP8 presentation: Objectives and expected outputs (Josep M Borras, ICO)

Equitable access to high-quality care and research: networks in the context of CCCs

Objectives: To assess how CCCs organize cancer care in the real world action of health systems at regional and local level, assessing the use of molecular tumour boards, ways of translating research progress into the networks, survivorship issues associated with follow up and return to work and potential uses of real world data to ensure equitable access to all cancer patients under the CCCs hub and spokes in each health system.

Question(s) & Answer(s):
Q1: At the moment, the focus is on tumour board, hoping that your data will show a broader connection between networks and CCCs. Another point is that patients should have equal

access to research and early phase RCTs through the network and not only from the CCCS. Is there any way that such information will come from your survey? It appears to be putting a strong emphasis of molecular TB compared to what happens on geographical terms.
A1: We chose to focus on molecular TB because they were designated across the network. Yet we will take this into account in the description of the process.
A2 (Sciensano): We have to try looking for national molecular TB, linked to molecular gene profile, to make sure that patients that are treated outside of CCCs could be included into RCTs (as some are only led by one single hospital in small countries like BE). Hopefully, this network might stimulate cross border collaborations.
A2 (ICO): Our idea was to map the diversity of approaches.
Comment (Sciensano): We should also consider links with other JAs, especially the JANE work package on high tech medical and others (discussing improved access to early clinical trials).

Q3 (CHU Brest): I understand the strategy but we don't treat the tumour but the patients. One site would only have the opportunity of 1-2 RCTs, but network could provide much more. In FR we have the 2 models. Patients could choose to stay in the same region, a very little percentage of patients is willing to travel. One needs to look beyond private, university and other centres, all together we are stronger.

Comment (ECPC): Within the scope of the WP, could we increase focus on cancer survivorship? Could we synchronise with previous initiatives, such as previous efforts on the topic initiated by the EC? They have done a thorough comparison within EU.
Comment: Different part of survivorship care are not always organized in the same way, CCCs and CCCNs could take that into account.

Q6: Instead of molecular TB, I believe that cross disciplinary meetings are more crucial than molecular TB. Clinical teams meet and decide therapeutic pathways and actions to take for each patient. These are organized at national/regional level and are more integrating the pathway than molecular TB. They haven't been surveyed.
R6: The task on molecular TB hasn't started yet, the protocol is being written and will be circulated. The WP7 would much like to participate in it as they have a great example of a network centred around clinical decision (cross disciplinary meeting rather than diagnostic meeting as molecular TB).

4. WP7 presentation: Objectives and expected outputs (Thomas Dubois, INCA)

Set of standards for research (incl. education) and set of governance standards of CCC
Main objective: Establish a framework for implementation of CCCs

Indicators:
- Process: Exhaustive mapping (based on survey)
- Output: One set of standards developed
- Outcome: Consensus model – will consist of the framework

Next steps (6 months):
- Framework: draft zero, planning and organisation
- Mapping: end of survey (April), 1st analysis and report, extensive analysis and report.

- Consultation: workshop work to define more precisely the standard, preparation for the stakeholder forum in Paris (Nov. 2023).

5. WP5 presentation: Objectives and expected outputs (ACC)

The objective is to create the EU network of CCCs.

WP 5's tasks:

1. Creation of Network of CCCs
    - Identification of the centres that are already certified.
    - Creation of new CCCs: by taking into account the regional context.
2. Develop a Governance model
3. Selection of evaluation criteria .

Question(s) & Answer(s):

Q1 (Luxemburg): Is it foreseen for the proposed model to be endorsed by MS? These modalities have to be assessed in more detail.
A: Of course, we are working with specific partners. We are missing the national representatives in defining the CCCs. We need to discuss about CCCNs and how other JA's models interact with each other.
A bis: the aim of the 1st meeting is for MS to guide us.
A bis bis (Tit Albrecht): the entire project is about 2 sides of the same coin even if they don't seem to be on the same coin. During the consultation meeting with EC and steering committee last Monday, 17th April, it was agreed that the implementation of JA will include other modalities in an evolutionary process.
Consensus is key yet we focus on inclusivity to deliver the network as it is set as the project's deliverable. I discussed this concern with the Commission, the definition is up to us but the mandate is one clear thing: national CCC in every MS.
The 2nd important question is that we have at least 4 categories of countries: (1) Long standing experience with CCC – bigger MS; (2) Multiple CCC accredited – typically in smaller MS (ex: Scandinavian countries); (3) Inexistant or under development CCC: concerned about the conditions; (4) outliers of smaller MS with specific challenges (to be clarified in next meeting).
Practically, while all MS participating will be included, we will have to proceed first by removing the outliers to set the guidelines and then adding it up.
The three smaller MS will have to connect to CCC of other countries, because they don't have the clinical capacity (not only about research) to ensure a good level of comprehensiveness. In addition to those, the challenges mentioned at the beginning: rare cancer, paediatric ones, etc.
The project deadline has been confirmed by the EC 2 months ago and it will not change: network will start in 2025.

Q2: Objection: MS are not equal already now, and we have experience of pre-existing models applied to outliers afterward that haven't worked in the past.
A: Hard to imagine a CCC will cover everything. The comprehensiveness is not in covering all cancer, but covering the most common conditions and will not change the national organization. E.g. bigger capacity for education & training and research is only possible when larger stretch ex university hospital.

One needs to look at how the whole process will evolve, by 2025 we will not reach the target set by the EC (not every MS will have a CCC). The evolution process takes 3-5 years according to the OECI's example. Many centres/countries where there isn't any CCC yet won't likely reach it. We have to provide a process to ensure they will reach it.
In the meantime, we will try to demonstrate how the findings of other running projects could be implemented in the future network.
Q3: Governance question: if some MS will be excluded by definition, how to ensure the inclusion of them at other levels?
A: MS cannot be excluded by definition. You can turn around the flagship of EBCP, if you are part of the process you cannot be excluded.
A bis: By wanting to include outliers more in WP7, instead of defining the type of models in the definition, one should aim for common level of academic output, patients, etc. with however some exceptions. Yet if you were to proceed the other way around at the level of small countries, e.g. Malta, you'd end up with thousands of CCCs. There is no intention of side lining smaller countries.
On the question of the governance of the network: We are being guided by the Commission. No MS has influence on what the European Reference Network (E-RN) does, they will have to treat the network as an autonomous entity. They need to be involved.

Q5: Are there criteria on the number of infrastructures? Given how ECBC sets clear thresholds (e.g. number of cases etc), one can fear that other organism(s) might influence these, by perhaps using action derived from professional recommendations and not from MS contexts. Referring to the expectations and influences, EBCP is quite an unique interesting document in EU history. It is by definition a top down document as it mandates MS to take action, that require investment on their side to reach targets (e.g. on screening coverage); investment in their public infrastructure on top of EU projects supporting it.
Are we going to lower or increase the standards? There are different challenges put forward besides the 3 smallest MS being located on islands except for Luxemburg.

Q6: How many tumours have to be comprehensively treated in a CCC? Perhaps this is a question for WP7. Secondly, does it mean that some regions with CCC (e.g. Italy) would lose their certificate? I cannot imagine they are bigger in scale than the one in Luxembourg.
A: WP7 has not defined it yet. Tomorrow we will present interesting information about cancer sites.
A bis: We developed this session more generally. We have so far been using the expression "MS should define", but to elaborate on this, we will have to ask MS to define whom are candidates.

Q7: Talking about threshold and referring to WP7, how do we define the success criteria: One would likely jump on the outcome of the CCC, but there could be activity at the network level to evaluate and improve this. The network itself should be characterized by continuous improvement and this needs to be measured and evaluated as of the 1st year.

Q8 :Portugal has an island – autonomy is asked to be a CCC, we need to receive guidance on how the MS should deal with policy on this.
A: There will always be challenges for smaller regions that we cannot avoid. E.g.: When

certification is -based on agreed thresholds, ifyour country's incidence is lower, one could only be granted 1 professional trained for a site.
Given national circumstances, this discussion is not about poor or excellent care: even having a CCC doesn't mean you have high quality care or the opposite. What we are talking about is the combination of various factors which sometimes do interplay with circumstances.

The process will be evolutionary and start from a starting point that won't be set in stone and untouched for many years. The entire oncology area is evolving very swiftly as do clinical guidelines.

The EC wishes to avoid the disinvestment of MS in the development of some of their centres implying they would have to send patients to other countries.
The most important issue is to establish link(s) between research and teaching. Each centre can develop it (1) Internally, (2) direct collaboration with centre/network, (3) By joining a network.

6. Synergies and overlaps among EBCP care-related projects: CraNE, CCI4EU, CCI, JANE (Sciensano)

Given that this project overlaps with the Europe's Beating Cancer Plan (EBCP), a mirror group was created last year in Belgium, to identify where there are gaps and opportunities. It unfolds in 10 technical working groups dealing with various aspects, involving representatives from each domain. We created a circular loop: we can provide input to the EC which writes calls.

The core elements for the rest of the cancer plan implementation are the following 4 dimensions: (1) CRaNE (GB's topic, launched by DG Santé), (2) parallel CCI4EU (about to start in May 2023, similar yet with focus on research for a better care, complementary), (3) JANE (new (technical) network of expertise – e.g. RTD), (4) CSA ECHOS (aims at something national and focus for RTD, create hub in countries to facilitate initiatives across countries).

Timeline:
New JA: CCI , network of expertise. Big joint action that we will have to feed; but for the proposal we need the outcomes of the previous ones. These JAs will only start when the previous JA will be finished, there are some flexibility from the EC.

Question "tour de table":

A) Why are we doing all of these things? Where do you see the benefit of such EU initiatives for your own country?

The mission of CRaNe is CCCs, the CSI will be a different story developed after that the project is finished and will focus on research and training

Q1: We have to approach it from several levels. Yet within a same hospital, various collaborators are dealing with different projects and we are not well aware of each other.
A (Sciensano): The role of the mirror group in Belgium is to know more or less what is going on, as we recognise it is hard to follow given the amount of information. Orion is about finding out

what is going on, support MS to know what is coming, etc. The upcoming challenge(s) is to combine hubs, CCCs, CCCN,… EC will provide continuous guidance.

B) Where do you see the benefit of such EU initiatives for your own country? Why do we do a European network/dimension?

Challenges of countries with fewer population is similar to the issues encountered by personalized medicine as everything becomes rare, hence European population are interesting as a whole. It is about how to structure the collection of information and data as well as how to exchange knowledge. We want to hear on this from the MS.
Q: What would be the next steps from the CRaNE perspective?
A: Will feed on the CCI JA directly, as a continuation. The stakeholder forum in the fall 2023 will be great to feed in the JA proposal CCI.
A (EC): MS are in the driver seat in the sense of developing proposal.

Regarding the legal status of the network:

- Not necessary to have a personality, exist as EUnetHTA network.
- Wont prejudice the legal status of CCC at national level, remains to the remit of MS legislation.

EC's Support :

- Annual program: financial envelope implemented on the basis of annual work program prepared by the EC.
- EU4Health program are in charge of the process and consulted during the interval. Steering group and program group composed as well of MS.
- Basically MS approve the work program and is then adopted by the EC.

7. Discussions with EU MS (tour de table)

Comment: There is huge ambition to lift EU, to be more competitive globally on cancer care beyond research. This looks very promising to compete with US for example.
EC: Various potential collaboration cross borders, perhaps with third country as the US, some contact with wider contacts of collaboration btw EU and US.

Q: CCI implementation based on CRaNE concept, will start after. At which moment do we learn that the concept developed with CRaNE is good ? How do we get the support to go into this direction?
A (EC): Ultimate test for the concept will be the follow up JA, in which further elements of the network can be extended and further develop links about cancer research eco system.

8. WP4: CraNE Maturity model (Dorota Dudek-Godeau)

The CraNE MM consists of a tool for monitoring the existing and pretenders to be CCCs and assess how they fit the concept and what are the next steps to become a CCC according to the

agreed concept.
The Maturity Model (MM) will include domains, reflected in WP7 criteria/definitions. Based on CCC definition, it will use wider concepts and integrate care based on results from WP6.
In Oct. 2023, we will search for volunteer MS to pilot the MM.

▶ Next objectives and methods for development of the MM (Prof Witold Szumowski)

- MM concepts: Some degree of complexities
- Objectives: several functions of MM
- Methods:
  - Step1 – review of MM areas
  - Step2 – determination of each need
  - Step3 – to be completed
  - Step4 – description of maturity's levels and examples of organisational solutions/development for individual dimensions. Output: research tool.
  - Step5 – testing model
  - Step6 – introduction of correction to the model
- Format and content: description of the MM, instruction for users, self-assessment survey template.

Each criteria can be described for different level of maturity, different organisation solutions.
→ most challenging step in this part of the project.

Example of maturity levels will be translated into survey questions to test the model and provide self-assessment map.

Question(s) & Answer(s):

Q1: Would it be useful to present results of the MM on a spiderweb diagram? Text and boxes are difficult to grasp while web diagram gives an overview.
A: It is complicated to use this kind of graphic presentation because of so many criteria. With scientific methods, we can translate into a quantitative method and show some average values for each dimensions, but it would be some kind of basic graphic presentation.
A bis: In the country holding the pilot, there will be a bunch of examples that will allow to compare and benchmark. We could discuss it when presenting the results of the pilos.

Q2: All sets of criteria for comprehensiveness of cancer centres are expressed in this model. When using OECI's assessment level, we also get that details from different angles. What does this maturity model give us as added value? Is it in addition or as a part of the certification?
A: While this has the potential to be used in certification processes, yet it isn't our goal in WP4. The added value of MM is to show the path and describe levels.
A: MM is a tool for a certain organisation to assess "how mature they are", where they are whereas the certification is an end point.
A (OECI): To populate the MM you need to populate it with data from certification core standard/process. There are various levels of deviations from the core standard, indicating you are not mature in a particular domain. Starting point: self-assessment of a centre on the ground against it.

A: MM shows a logical pathway, steps to grade actions to take. Adapt the level to match the criteria we define. This is done in certification when creating an improvement plan. Need to see if these would fit and it will be challenging.

Comment
One cannot be sure that all certified centres will have the highest maturity according to all citeria/measurements axes. The development of some domains may be well above or below what is required by the certification standards. That said, it could be interesting to apply the maturity criteria to certified CCC to assess how mature they are.

Q: We need to anticipate one problem: Showing there is only one way to maturity. How does one need to adapt a generic model, having limitation/weakness of being applied?
A: In some area(s), you can describe the variety of ways to reach maturity, but the weakness of this tool is to draw one main path.
A bis: In certain dimension(s), some criteria will be overlapping. We need cohesion of criteria and to make sure to not duplicate areas of criteria in pilot.

Q: Will we be able to fill in all the levels for all the dimensions in such a short timeframe?
A: This is a problem when we have 0/1 indicators. We could group them in sub-dimensions, in some kind of indicators based on Goodman's idea. E.g. Do we have standards for each of the dimensions? Level 4: Comply with the standard Y/N.

Q : MM could also be used to support centres on their way towards CCC. The MM is yet too complex. The columns on top are confusing, it might be easier to display 1 to 5 as it was done for cohesion. Detailed levels could be defined elsewhere.
We need to note that level 1 should be the start, not 0 (would make it difficult for analysis).
A: Levels of maturity will be for criteria that are in the dimensions. It provides an overview on everything. If we would look at each dimensions at a time, it wouldn't look as complex as this. We have to wait for the criteria, check how much they overlap, for this cohesion table – we will decrease the number of criteria when they overlap, and then we will look on maturity levels.
Abis: MM relates to quality not quantity; will focus on organizational solutions, not on quantitative measures.
Comment: Yet we cannot divide the two (quality and quantity).

- Blueprint and next steps (Sciensano)

The BP will be a detailed and stepwise approach for centres at local level to join the EU NCCCs; will integrate MM and results from WPs5-8.
Thematic supporting tool – each step relating to specific theme/domain and challenges related to sustainability. It focusses on contextual features, as socio-cultural-welfare systems elements can interfere with implementation process of CCCs.

Objective: Very practical and visual output to support countries and ensure sustainability of the EU NCCCs.
Methods: Use results from WPs to identify themes and steps to be included (+examples).
Identify broad contextual features: facilitators and barriers, will vary across countries,

organisations. E.g. partnership and collaboration: legal framework could be heavy in some regions; for others it'd be workforce that needs to adapt.

Ongoing: Review about what exists in terms of blueprint (for the format); what are the key determinants of sustainability? What could hinder the implementation, the further development and the long-term run?

Format: extracted from the lit:

- Provide a broad overview of all steps and domains
- Link with outputs from WPs 5-8
- Contextual features integrated (as exhaustive as possible) to capture what can affect development, implementation and sustainability
- Timing will likely be very different across countries (try to integrate examples based on the test phases from the MM)
- Need to think of interactions amongst steps and themes especially when they have an impact on timing on one to another, or sequential conditional steps (= arrows)

Example of visualization:

- Overview
- Different theme to reach the ideal situation

Content: Fit with concepts addressed in WPs (7 and 5 especially)

9. Overall conclusion of this 1st GB's meeting:

Next (2nd) Governmental Board's meeting in Oct. 2023
Do not hesitate to work on the minutes together and comment when they will be shared.

Norway: Could be useful to have some lessons learned from this meeting:

- All presenters should be present.
  → Next meeting will be a preparation of the next JA, ask everyone to be present. Make it only presential and not hybrid mode.

France suggested to have before summer a WP leader retreat/meeting for several days out of office to clarify some issues.
Slovenia: For some point, such as the one of LU raised today, this is very adequate.