TOOL 11

Questions people should consider when approaching a new collaboration between ERNs and Industry

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This resource consists of a list of key questions which should be considered by anyone contemplating a collaborative activity between an ERN (or ERNs) and Industry (whether single company or multiple). The questions stem from the survey initially used to support the selection of the Together4RD pilot projects, updated in light of the the lessons learned from the pilot initiation process.

It is intended as merely a guide, for all parties (public and private), to help stakeholders ensure they enter into co-creation and negotiations with the best chance of success. Specific and realistic expectations are important, to maximise the efficiency of those early discussions, and hopefully avoid some of the pitfalls that can occur and delay or even jeopardize a public-private collaboration. This should be viewed in connection with Tool 9 **Lessons Report on the Experiences and Learnings from the first ERN-Industry pilots supported by Together4RD** and Tool 10 **Key recommendations for both ERNs and industry from the experiences of the first ERN-Industry pilots**.

Objectives / expected outcomes of the collaboration

- What are the overall and specific objectives of the project/collaboration?

- How does the proposal link to wider priorities (for the ERN(s), industry, patients, or the broader policy/Research & Development ecosystem)?

- When would you be ready to start?

- What would a reasonable timeline be for this project to be delivered?

- Would it be a one-off distinct project or do you envisage it as the first step in a longer collaboration?

- Would this project be suitable for multiple ERNs and/or multiple companies to embark upon together? Or is it a single ERN-single company collaboration?

- Are any organisations beyond the ERN(s) and the company(ies) going to be directly involved?

- How would you ensure the ERN(s) supports and shapes this, beyond a single researcher or centre (e.g. has this been discussed in the relevant governance boards? Or research working groups or networks?)

- Are there any areas or outcomes of the project which are non-negotiable?

Expertise and Resources

- Is there already any established infrastructure or data on which this project could/should build?

- If so, who owns this/how can you access or use it?

- If a registry or registries are involved, who owns the data, what kind of data access agreements are already in place, etc.

- What types of expertise and *non-financial* resources would be needed? (thinking in terms of technical expertise, scientific expertise, training, etc)

- Who, within the planned consortium, can bring each kind of expertise and resource?

- How do you plan to involve patients/ a relevant patient organisation?

Funding

- What level of budget would be required to meet the project goals you have in mind at this stage?

- What would be the key milestones in this project, and what kind of budget would each require?

Process Considerations

- Would one party drive this forward overall, or lead on particular stages/areas of work?
  - Who is ultimately responsible for keeping the project planning, and the implementation, on track?

- Do you have commitment from senior leadership in all respective parties, for project sign-off and for financial issues?

- Who would provide dedicated project management time for the project, and how?

- Would the project involve accessing or collecting patient data (and is it retrospective

or prospective data)?

- Do you need to engage/access data for a minimum or maximum number of patients?

- Would the project require ethics approval?

- Have you involved legal and compliance teams in all prospective partner institutions? How will you ensure the smoothest possible approvals process?

- What risks would you foresee?
  - And what actions could you envisage to mitigate these?

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