

## D4.3 PARADIGM Patient Engagement Toolbox

**777450 - PARADIGM**

*Patients Active in Research and Dialogues  
for an Improved Generation of Medicines*

### WP4 – Co-designed recommendations and resources for patient engagement

<b>Lead contributor</b>	1 - European Patients' Forum – Mathieu Boudes 12 - The Synergist – Chi Pakarinen  <a href="mailto:mathieu.boudes@eu-patient.eu">mathieu.boudes@eu-patient.eu</a> <a href="mailto:chi@thesynergist.org">chi@thesynergist.org</a>
<b>Other contributors</b>	EUPATI (External) - Maria Duterte & Camilla Habre 19 - Bayer – Wolf See

<b>Due date</b>	31/08/2020
<b>Delivery date</b>	20/09/2020
<b>Deliverable type</b>	R
<b>Dissemination level</b>	PU

## Table of Contents

Table of Contents .....	2
Document History .....	2
1. Publishable Summary .....	4
2. Introduction .....	4
3. The PARADIGM PE Toolbox.....	4
4. Limitations .....	16

## Document History

Version	Date	Description
V0.1	06/03/2020	First Draft
V0.2	10/04/2020	Edited first draft, ready for review by consortium members
V0.3	30/07/2020	Final draft ready for external reviewers
V0.4	20/09/2020	Final Version

**Partners of the PARADIGM Consortium are referred to herein according to the following codes:**

- **EPF.** EUROPEAN PATIENTS FORUM (Luxembourg) – **Project Coordinator**
- **EURORDIS.** EUROPEAN ORGANISATION FOR RARE DISEASES ASSOCIATION (France)
- **EATG.** EUROPEAN AIDS TREATMENT GROUP (Germany)
- **AE.** ALZHEIMER EUROPE (Luxembourg)
- **AIFA.** AGENZIA ITALIANA DEL FARMACO (Italy)
- **HTAi.** HEALTH TECHNOLOGY ASSESSMENT INTERNATIONAL (Canada)
- **IACS.** INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD (Spain)
- **FSJD.** FUNDACIO SANT JOAN DE DEU (Spain)
- **VU-ATHENA.** STICHTING VU (The Netherlands)
- **UOXF-CASMI.** THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD (United Kingdom)
- **EFGCP.** EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE (Belgium)
- **SYNERGIST.** THE SYNERGIST (Belgium)
- **EFPIA.** EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS (Belgium) - **Project Leader**
- **MSD Corp.** MERCK SHARP & DOHME CORP (United States)
- **UCB.** UCB BIOPHARMA SPRL (Belgium)
- **ABPI.** THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY (United Kingdom)
- **AMGEN.** AMGEN LIMITED (United Kingdom)
- **BAYER.** BAYER AKTIENGESELLSCHAFT (Germany)
- **GSK.** GLAXOSMITHKLINE RESEARCH AND DEVELOPMENT (United Kingdom)
- **GRT.** GRUENENTHAL GMBH (Germany)
- **JANSSEN.** JANSSEN PHARMACEUTICA NV (Belgium)
- **LILLY.** Eli Lilly and Company Limited (United Kingdom)
- **LUNDBECK.** H. LUNDBECK AS (Denmark)
- **MERCK.** MERCK KOMMANDITGESELLSCHAFT AUF AKTIEN (Germany)
- **NOVO NORDISK.** NOVO NORDISK A/S (Denmark)
- **PFIZER.** PFIZER LIMITED (United Kingdom)
- **ROCHE.** F. HOFFMANN-LA ROCHE AG (Switzerland)
- **SERVIER.** INSTITUT DE RECHERCHES INTERNATIONALES SERVIER (France)
- **VFA.** VERBAND FORSCHENDER ARZNEIMITTELHERSTELLER EV (Germany)
- **SARD.** SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT (France)
- **NOVARTIS.** NOVARTIS PHARMA AG (Switzerland)
- **COVANCE.** COVANCE LABORATORIES LTD (United Kingdom)
- **ALEXION.** ALEXION SERVICES EUROPE (Belgium)
- **TEAM IT.** TEAM-IT Research (Spain)

- **Consortium.** The PARADIGM Consortium, comprising the above-mentioned legal entities
- **Consortium Agreement.** Agreement concluded amongst PARADIGM participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

## 1. Publishable Summary

The PARADIGM Patient Engagement (PE) Toolbox is created to centralised PARADIGM’s co-created recommendations, tools and relevant background information in one place in order to effectively facilitate their dissemination by the consortium partners and subsequently, following the completion of PARADIGM as an IMI project, their availability through external partners and supporters. The PE Toolbox also provides a structure and context within which the individual tools can be interlinked.

This document describes the main features of the PE toolbox, its accessibility channels via the main PARADIGM website as well as both the EUPATI and PFMD websites, the IT and technical specifications, the visual identity opportunities and limitations and requirements for hosting a version of the toolbox by external organisations

Finally, this document outlines the tentatively future aspects of the PE Toolbox’s sustainability in line with the recommendations laid out in D6.4 Sustainability of the PARADIGM outputs.

## 2. Introduction

This document outlines the guidance and recommendations for the creation of the PARADIGM Patient Engagement Toolbox (referred to as PE Toolbox in this document). It contains the IT specifications, the definition of the minimum viable product, the requirement for accessibility from both PFMD and EUPATI websites and beyond, the coherence, the visual identity, the sustainability elements and the limitations.

The *minimum viable<sup>1</sup> product* of the PE Toolbox is an iteration of the product that will have sufficient core features to effectively deliver value to its users, but might not represent the final product yet. This strategy helps to avoid building features that users do not want, and seeks to maximise utility, and minimise redundancy, whilst accepting improvements and enhancements can be made later. The minimum viable product can then be improved and enhanced based on usage experience, user feedback and external developments. The minimum viable product of the PE Toolbox will include aspects of functionality, design, reliability, and usability<sup>2</sup>.

## 3. The PARADIGM PE Toolbox

### What is the PARADIGM PE Toolbox?

The PE toolbox is created to centralise all PARADIGM’s co-created recommendations, tools and relevant background information in one place in order to facilitate their dissemination by the consortium partners and later on, after the end of PARADIGM as an IMI project, their availability through external partners and supporters. The PE Toolbox also provides a structure within which the individual tools can be interlinked.

“The overarching mission of PARADIGM is to develop a framework that allows structured, meaningful, sustainable and ethical patient engagement (PE) throughout three key decision-making points of the development of medicinal products (prioritisation of research, early dialogue between regulators and HTA and design of clinical trials)”<sup>3</sup>. With this objective and the inherent nature of a ‘public-private’ partnership in mind, the PE Toolbox follows certain principles from the start. One such principle is that the main tools and guidances

---

<sup>1</sup> “A Minimum Viable Product is the smallest thing you can build that delivers customer value (and as a bonus captures some of that value back).” (Maurya, 2017. Accessible here: <https://blog.leanstack.com/minimum-viable-product-mvp-7e280b0b9418>)

<sup>2</sup> Adapted from [https://en.wikipedia.org/wiki/Minimum\\_viable\\_product](https://en.wikipedia.org/wiki/Minimum_viable_product)

<sup>3</sup> IMI-PARADIGM approach and goals derived from the original proposal. Accessible via PARADIGM website at: <https://imi-paradigm.eu/our-approach/>

co-created within the IMI public-private consortium should be freely accessible and without requirements for any kind of registration or data collection.

The PARADIGM consortium will, to the best of its ability and within its limited timeframe, accommodate accessibility considerations (both in the tools as well as in the toolbox) to reach appropriately as many users as possible. However, the translation of the tools was not originally planned and not foreseen as part of the deliverables. Whilst some of the data gathering took place multi-lingually, the tools and the toolbox are produced in English only under the PARADIGM project.

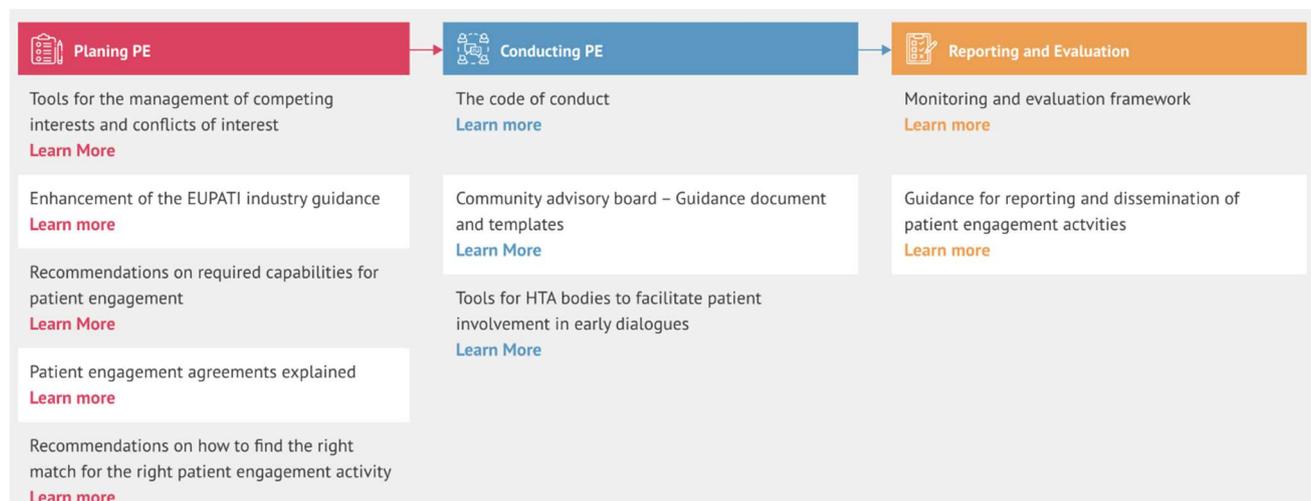


Figure 1: Interlinked tools within the PE Toolbox

The PE Toolbox will be hosted on imi-paradigm.eu website and can be accessed by anyone with an internet connection. The tools within the PE Toolbox can also be downloaded and used offline as exported documents. The PE Toolbox and single tools in it can be linked to on other platforms to increase dissemination and accessibility, but only if the specific requirements set out in this document are met.

## Tools

The background work done early in PARADIGM -identification of stakeholder’s needs and expectations, creation of criteria to assess PE practices, a gap analysis of current PE practices against the needs and expectations - has led us to this specific set of tools. Some of these tools address needs at one of the three specific decision-making points and others have broader applicability. The common denominator is they have all been co-created within the multi-stakeholder consortium, have been reviewed by the Paradigm International Liaison Group (PILG)<sup>4</sup> and undergone a public consultation.

The tools in the PE Toolbox are described below. Please note that the descriptions below have been gathered from the relevant working groups as ‘work in progress’ and the final descriptions and format might differ slightly, once the tools are ready for the public. Detailed and final descriptions of the tools will be found on the PE Toolbox by the end of September 2020.

<sup>4</sup> More info about the PILG: <https://imi-paradigm.eu/paradigm-international-liaison-group/>

Name of the tool	Description	Format
Monitoring and evaluation framework	A practical and usable tool, to select metrics relevant to the PE activities for monitoring and evaluation purposes	Interactive document
Code of Conduct	<p>This ‘Code of Conduct’ for all stakeholders involved in patient engagement activities within medicines development” is intended to be a stand-alone document that highlights, summarises and refers to the key patient engagement principles, rules, and recommendations for collaboration presented in the different PARADIGM documents in a comprehensive, understandable format.</p> <p>It was jointly developed by a large team of experts to reduce the risks of conflicts and hurdles in patient engagement activities by defining the conditions for fruitful collaboration.</p>	PDF
Recommendations on required capabilities for patient engagement	<p>This document provides recommendations on a set of capabilities and competencies (understood as knowledge, skills, and behaviours) that each stakeholder should aspire to have in place in their respective organisation, to be able to plan, implement, and reflection on PE activities.</p> <p>The objective of the recommendations described is to strengthen ‘system readiness’ across all stakeholder groups, to ease and systematise patient engagement by identifying the capabilities required. Stakeholders can use these recommendations to analyse their own organisation’s capabilities and consider the elements described to further develop or adapt their capability model.</p>	PDF
Tools for the management of competing interests and conflicts of interest	<p>Managing competing interests and conflicts of interest is of utmost importance when planning, considering and conducting patient engagement activities.</p> <p>This document:</p> <ul style="list-style-type: none"> <li>• raises awareness among patients, in their role of experts by experience, and the engaging stakeholder organisations of the consequences that the act of engagement might have on patients during multi-stakeholder interactions</li> <li>• highlights how each stakeholder could better prospectively manage competing interests</li> <li>• helps to avoid/minimise conflict of interest by suggesting risk mitigation strategies.</li> </ul>	PDF
Enhancement of the EUPATI industry guidance	<p>The EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&amp;D); Guidance for Pharmaceutical Industry-Led Medicines R&amp;D was published in Frontiers in October 2018. During the PARADIGM project, further expansion of specific sections of EUPATI guidance was undertaken.</p> <p>Set of tools created:</p>	PDF

	<ul style="list-style-type: none"> <li>• Enhanced EUPATI guidance: suggested working practices             <ul style="list-style-type: none"> <li>○ Suggested working practices checklist</li> </ul> </li> <li>• Enhanced EUPATI guidance: events and hospitality             <ul style="list-style-type: none"> <li>○ Events and hospitality checklist</li> </ul> </li> </ul> <p>The working-practices guidance provides detail on how an interaction could be defined with specific actions and describes what should happen during pre-engagement planning and discussions to ensure mutually beneficial interactions with adequate preparation.</p> <p>The events and hospitality guidance provides more detail on the level of attention needed when arranging patient engagement activities to ensure patients have the best experience.</p>	
Community Advisory Board – Guidance document and templates	<p>Community Advisory Boards (CABs) are an innovative concept, developed originally in the United States and more recently in Europe, to establish long-term relationships between the patient community and industry, to encourage ongoing patient engagement in a disease area, including but not limited to the lifecycle of a specific medicine</p> <p>There are a number of patient communities working with CABs. Although other ways of collaboration between patients and industry exist, a key element of this approach is that CABs are initiated and driven by the patient community and their work is independent of (but often funded by) industry.</p> <p>The PARADIGM CAB toolkit contains 8 different tools. The toolkit has been developed collaboratively by people from the patient community and from industry both with and without experience in CABs and is intended for patient communities and pharmaceutical companies interested in setting up, running, or collaborating with CABs.</p>	PDF
Patient engagement agreements explained	<p>Collaboration between pharmaceutical companies and patient advocates should be based on contracts signed by both parties covering various types of activities such as consultancy, collaborations, speaking engagements and advisory boards. These contracts define the terms and conditions of the engagements, covering such matters as confidentiality, intellectual property, copyright, data protection, compensation and other responsibilities of both parties. They typically also contain provisions, mandated by the pharmaceutical industry or regulatory authority codes, designed to ensure an appropriate relationship between a patient and the engaging partner. In the past, the complexity of these agreements has often been challenging for the patient community and in particular patient advocates to work with due to the contracts being long, difficult to understand and sometimes containing ambiguous clauses.</p> <p>This work aims to help the patient community to understand the agreements they might need to review when collaborating with pharmaceutical industry. The digital tool shows the reference agreements co-created by WECAN (under the RAPP project) with additional explanations co-created and reviewed within a multi-stakeholder task force in PARADIGM.</p>	PDFs and online tool

Recommendations on how to find the right match for the right patient engagement activity	This document provide recommendations to all stakeholders to identify the right match for the right patient engagement activity. They address the topics to consider and a check list of the elements to consider before engaging with a patient organisation. It is complemented with a table of competencies, as a tool for individuals to self-assess their own competencies, as well as during the co-design phase to identify the level of competencies required for the activity.	PDF
Guidance for Reporting and Dissemination of Patient Engagement Activities	<p>The complete and reliable reporting and dissemination of all patient engagement (PE) activities is essential to ensure transparency and enable continuous broad learning for all relevant stakeholders undertaking PE activities. Progress is best achieved through an agile learning ecosystem.</p> <p>The purpose of this tool is to address issues specifically related to the reporting of PE activities in the public domain. It builds upon relevant principles of reporting clinical trial data, 'case study' formats of PE activities on open access platforms, and standardized publishing of PE projects in journals.</p> <p>In so doing, this document provides participating organisations with guiding principles, a planning checklist, and a practical template to move beyond anecdotal reporting of broad PE strategies, to promote consistent, timely, accessible, and findable PE activities as part of a learned dissemination and communication continuum.</p>	PDF
Tools for HTA bodies to facilitate patient involvement in Early Dialogues	The Patient Engagement in HTA Early Dialogues tool is a resource of factsheets, templates, and adaptable tools for use by HTA agencies to help them better prepare for patient engagement. The tool consists of three main sections: The rationale and context of patient engagement in early dialogues; an overview of the main methods of patient engagement used during the early dialogue process; a range of templates, checklists and resources to assist with conducting patient engagement in early dialogues.	PDF

## IT and technical specifications

This section defines and describes the IT (Information Technology) and technical requirements to produce and host the PE Toolbox on the existing PARADIGM website, and to prepare the partner websites (SYNAPSE by PFMD and EUPATI) to link and promote the PE Toolbox in the easiest most efficient and coordinated way. The two partner websites also act as examples of how the PE Toolbox can be made accessible and promoted by other stakeholders.

The operational set up is done in two stages, each of which is done in an iterative manner to ensure that the end product meets the minimum requirements and provides a product that can be delivered in the last few months of PARADIGM. Since the PARADIGM project ends in November 2020 (for all but communication and project management work packages), the website is redesigned with a goal of needing only a minimum level of maintenance in the next 3-5 years.

## Stage 1 - Repurposing the PARADIGM website

The PARADIGM website is repurposed from an awareness and knowledge-sharing website to become a host of the various tools being created (a digital toolbox). Adhering to the minimum viable product principle, by the time the project closes, the toolbox will be a version that has sufficient core features to effectively deliver value to its users.

The website will be revised, reorganised, redesigned and developed with accessibility considerations<sup>5</sup> in mind. A search function is implemented to ease the users' search for the tools they need, and depending on the format of the tools, some might be able to be used online, and others exported. To comply with the General Data Protection Regulation<sup>6</sup>, no personal user data will be collected or stored on the website.

Operational milestones include

- securing the domain name for the next 3-5 years by the Synergist and EUPATI with a cost-sharing process to be further agreed between the two entities,
- creating and testing solutions for the PE Toolbox through iterative wireframing,
- development of the actual page on the PARADIGM website,
- uploading, indexing and interlinking the tools to provide a coherent toolbox and to enhance the user experience,
- testing the final product and testing the linkages with partner websites.

The architecture of the PE toolbox will be structured as one main (landing) page with a specific sub landing page for each of the tools (with a specific URL that is structured like this:

[www.imi-paradigm.eu/toolbox/'nameofthetool'](http://www.imi-paradigm.eu/toolbox/'nameofthetool'). Each page will display an introduction of the tool, its purpose and the target audience. This will be further decided by each of the working groups creating the tools in the IMI PARADIGM T4.2.

## Stage 2 - Developing the interconnection with two partner websites (PFMD SYNAPSE and EUPATI)

PFMD<sup>7</sup> and EUPATI<sup>8</sup> have been identified since the beginning of the project as two existing and viable options for the sustainability dissemination of the PARADIGM tools. As the two websites are constantly evolving, some preparatory work has been identified for the two platforms in order to provide an optimal environment to access the PARADIGM tools. These websites will link to the PE Toolbox, but will not host the tools. Upon users' search, the user will be directed to the PARADIGM website where all original tools are hosted.

On SYNAPSE (the PE platform for PFMD), the tools will be linked under the *Resources*- functionality, which is a searchable repository of user-shared PE resources (usually) linked to related PE initiatives or events. The PARADIGM PE toolbox will be disseminated within this functionality. On the EUPATI website, the tools will be linked under a dedicated section on the Medicines R&D Toolbox and Patient Engagement Toolbox, a searchable online library.

Operational milestones include:

- rethinking current functionalities on both websites to accommodate proper linkage to PARADIGM PE Toolbox,
- user-experience considerations within the design and development,
- updating search functionality with fields, filters and badges relevant to the PARADIGM PE toolbox,

<sup>5</sup> For example: <https://ukhomeoffice.github.io/accessibility-posters/posters/accessibility-posters.pdf>

<sup>6</sup> Find out more about the GDPR from the European Commission's website, accessible here: [https://ec.europa.eu/info/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules/eu-data-protection-rules\\_en](https://ec.europa.eu/info/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules/eu-data-protection-rules_en)

<sup>7</sup> PFMD's mapping and networking platform Synapse has been created for any users to share PE best practices, map anything and everything related to PE and visualise the PE ecosystem globally. Access Synapse here: [www.synapse.pfmd.org](http://www.synapse.pfmd.org)

<sup>8</sup> EUPATI is a public-private partnership, established as an independent Foundation (as of 2020). EUPATI focuses on education and training to patients and other stakeholders about medicines R&D and patient engagement. It also aims at making objective, reliable and patient-friendly information about these areas available for the public. Access EUPATI here: <https://www.eupati.eu/>

- in the backend: technical refactoring of resource management on both SYNAPSE and EUPATI platforms,
- testing & validation of SYNAPSE & EUPATI linkages to imi-paradigm.eu,
- and finally, approval and launch of the PE Toolbox as a whole.

### **Provision to add new or update existing tools**

Due to the finite nature of the PARADIGM project, there is no opportunity for maintaining and updating the tools or the PE Toolbox by the PARADIGM consortium partners (with few exceptions as described in D6.4). However, with the Synergist and EUPATI's commitment to sponsor the domain name and provide a minimum level of maintenance, the website and the PE Toolbox are secured to be accessible in the next 3-5 years. Details of this collaboration will be specified in a separate agreement between the two organisations. The tools (at the time of writing this report) will remain as such after the launch, unless the authors of the tools decide to update their tools after the end of PARADIGM in August 2020.

The PE Toolbox is a PARADIGM deliverable and as such will not integrate externally developed tools. The individual tools might reference to other existing resources outside of PARADIGM, but in itself the toolbox will only contain PARADIGM tools. The option of hosting tools from other stakeholders was discussed and considered as being beyond the scope of PARADIGM.

### **Accessing the PE Toolbox**

As described above, the PE Toolbox will be hosted on the PARADIGM website, however, in order to manage associated costs (branding, referencing, online advertisement) and to leverage existing collaborations, it was agreed to ensure the accessibility of the toolbox through two established and well known platforms that are SYNAPSE (operated by PFMD) and EUPATI. Described below is how to access the tools from the PFMD/ SYNAPSE and the EUPATI websites.

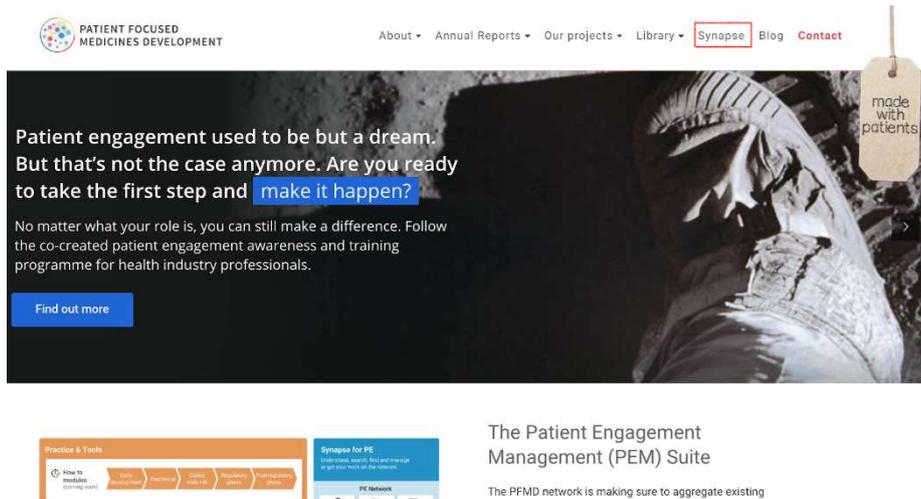
#### **▪ From PFMD website**

Resources (I.e. any project outcomes and/ or supportive material ranging from reports to presentation, videos, publications, etc.) from different organisations and events can be accessed through the Resources functionality in SYNAPSE, as shown below. For the PARADIGM PE Toolbox, this linkage will be improved as described in the IT specifications section above.

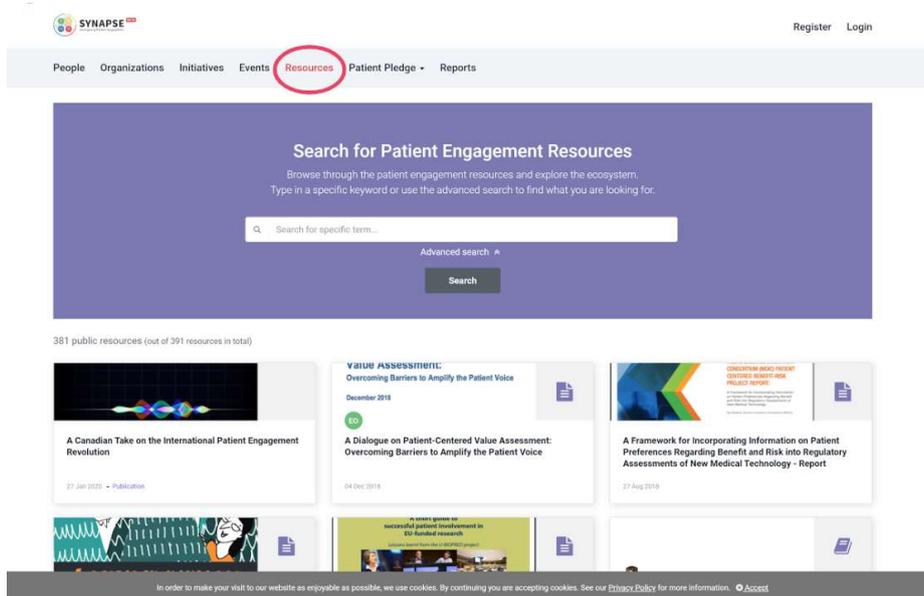
#### **Current setup:**

SYNAPSE can be used without registering or logging in to the platform. Anyone interested in exploring the PE network and related initiatives, people, organisations, events and resources may do so directly from the platform's website and access resources that are shared publicly.

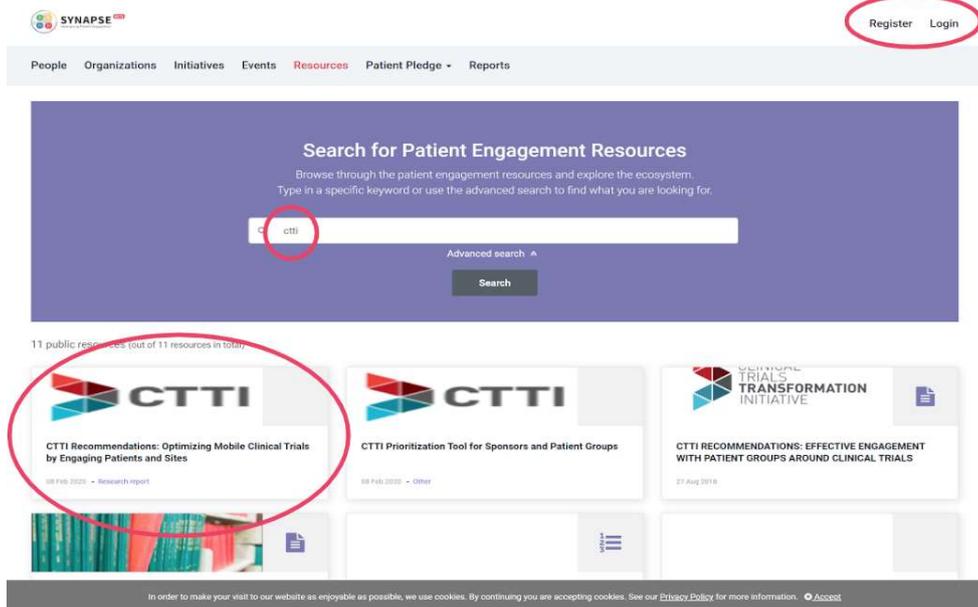
- Step 1 - Access Synapse via [PFMD homepage](#) or directly on [www.synapse.pfmd.com](http://www.synapse.pfmd.com) (go to step 2)



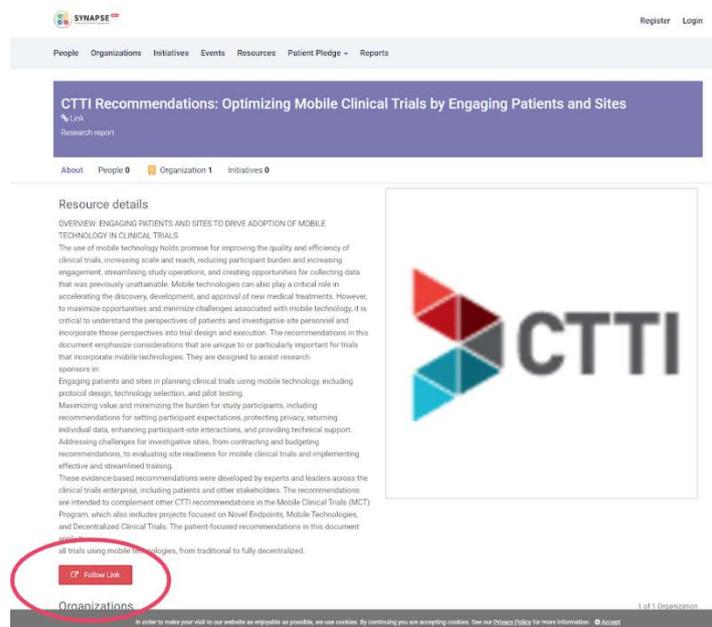
- Step 2: click on 'Resources' and the functionality opens up with a search engine.

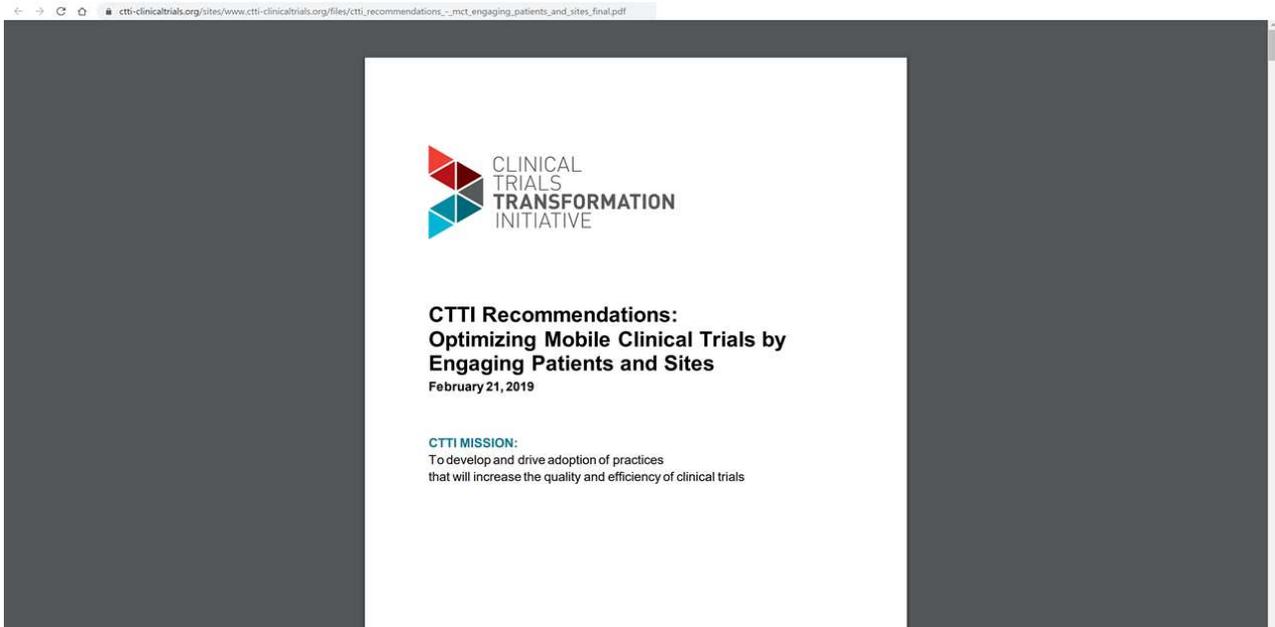


- Step 3: Use the search box to enter the key words for what you are looking for. In this example, the user wants to search for CTTI's tools, specifically one that's entitled '*CTTI Recommendations: Optimizing mobile clinical trials by engaging patients and sites*'. Upon typing CTTI in the search field and clicking "Search", all CTTI resources available on SYNAPSE (both uploaded to SYNAPSE or hosted on CTTI 's website) will appear as search results.



- Step 4: Click on the results of interest. A detailed description of the tool/resource/material is displayed together with a potential link to download or access further from the organisation’s website. In this case, the resource had an additional link (see next image).
- Step 5: Click on ‘Follow Link’ to access the resource at its source (in this example, the website will redirect you to CTTI’s website).



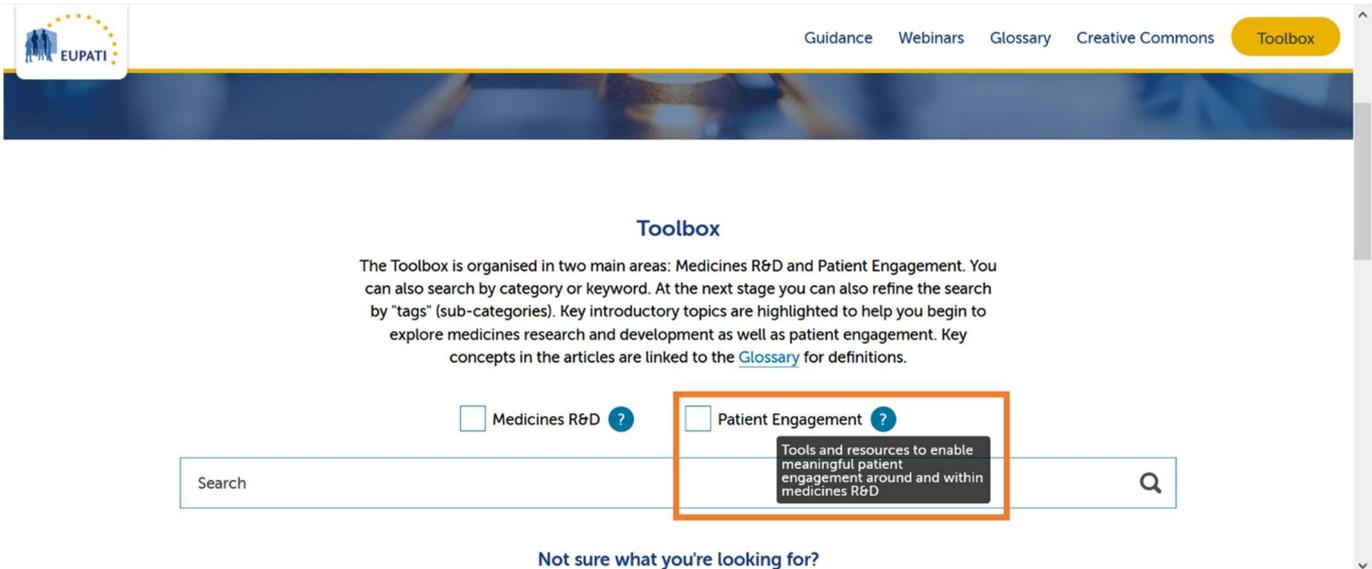


- From EUPATI website

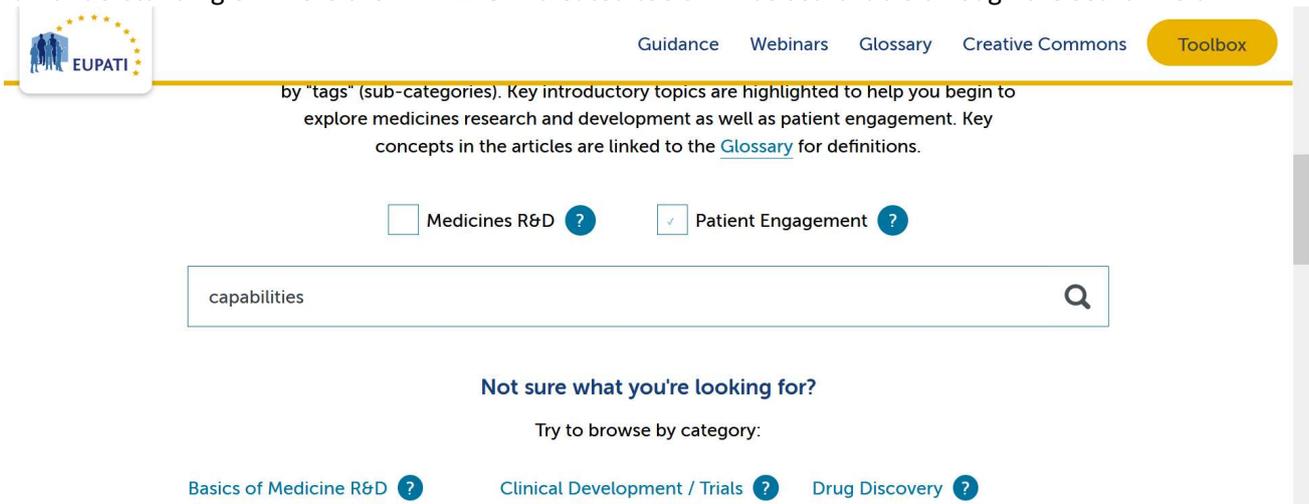
- Step 1: Access the EUPATI website from [www.eupati.eu](http://www.eupati.eu)



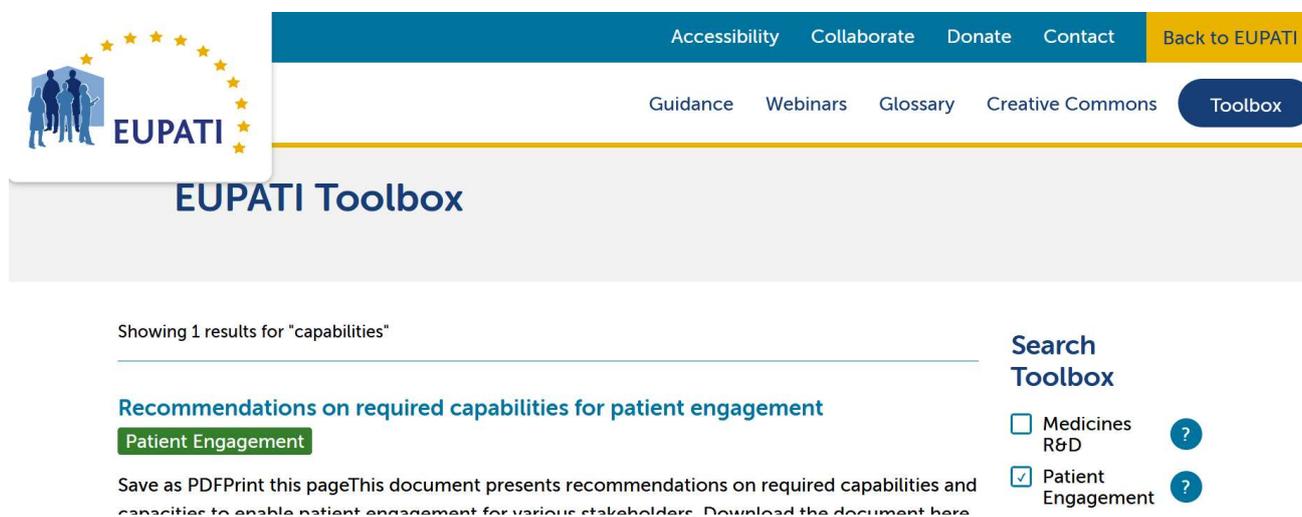
- Step 2: Click on 'Toolbox' and you will access the EUPATI Medicines R&D Toolbox and Patient Engagement Toolbox page



- Step 3: Enter key words in the search field for Patient Engagement Toolbox  
While this page is still under development during the drafting of this report, the mock-up image below gives a fair understanding of where the PARADIGM-created tools will be searchable through the search field.



- Step 4: Search results (links to different documents) will appear on the screen. If a PARADIGM tool appears in the selection and you select it, you will be guided to the PARADIGM website, directly to the page that hosts the tool.



The screenshot shows the EUPATI Toolbox website interface. At the top, there is a navigation bar with links for Accessibility, Collaborate, Donate, Contact, and Back to EUPATI. Below this is a secondary navigation bar with links for Guidance, Webinars, Glossary, Creative Commons, and a prominent Toolbox button. The main content area displays a search result for "capabilities". The result is titled "Recommendations on required capabilities for patient engagement" and is categorized under "Patient Engagement". A "Save as PDF" button is visible. To the right, there is a "Search Toolbox" section with two filters: "Medicines R&D" (unchecked) and "Patient Engagement" (checked). Both filters have a question mark icon next to them.

## Opportunities to feature the PE Toolbox by other organisations

PARADIGM tools have been co-created by stakeholders who recognise the need to collectively make PE in medicines R&D easier for all by lowering the entry threshold in this field. With this in mind, anyone or any individual or any organisation that aligns with the principles of sharing knowledge and jointly building PE capacity are encouraged to link to and share the PARADIGM PE Toolbox and its content. In order to do this in a coordinated way to ensure the maximum impact, the following provisions should be adhered to if and when PARADIGM's resources are shared:

1. **The visual identity** needs to be strictly adhered to, no deviation or adaptations are permitted for resources that are shared as PARADIGM tools.
2. All PARADIGM resources are **free to access and use** and shall not require users to fill in any forms, registration or logging in on any sites or services.
3. In addition to the above, if included on an external organisation's server,
  - a. all accessible content must be linked to the original PE Toolbox on the PARADIGM website,
  - b. **reference to the IMI PARADIGM and project funders** should be clearly visible,
  - c. the organisation is responsible for making sure they are always referring to the most up-to-date content versions and the original PE Toolbox.

## Visual identity, IMI PARADIGM project funders and PARADIGM partners visibility

In order to emphasise the 'public-private' partnership nature of the co-creation of the tools, as well as to acknowledge the funding bodies, and have a coordinated strategy to disseminate and promote future tools, it is paramount to retain the PARADIGM visual identity for the PE Toolbox and tools (in relation with the PARADIGM T4.2); although the decision at the beginning of the project was that PARADIGM should not be considered as a brand, acknowledging its finite nature. The visual identity of the PARADIGM PE Toolbox will follow the guidelines created at the beginning of the project (submitted as a deliverable<sup>9</sup>).

<sup>9</sup> [https://imi-paradigm.eu/wp-content/uploads/2018/05/18-MAY-28\\_Deliverable-5.3-Digital-assets-including-website-FINAL.pdf](https://imi-paradigm.eu/wp-content/uploads/2018/05/18-MAY-28_Deliverable-5.3-Digital-assets-including-website-FINAL.pdf)

Also following the IMI JU2 guidelines, the funding bodies of the PARADIGM project will be clearly visible on the website (and any website that links to the PE Toolbox). Therefore, the following text will be clearly visible on the homepage of the PE Toolbox and on all tools:

*'PARADIGM was a public-private partnership (2018-2020) and was co-led by the European Patients' Forum and the European Federation of Pharmaceutical Industries and Associations (EFPIA). PARADIGM received funding from the Innovative Medicines Initiative Joint Undertaking 2. This Joint Undertaking received support from the European Union's Horizon 2020 research and innovation programme and EFPIA'.*

Finally, the 34 partners of the PARADIGM consortium will have their logos clearly visible on the PE Toolbox as currently (March 2020) shown on the [project partners page](#)<sup>10</sup> on the PARADIGM website.

### **Recommendation for future sustainability**

The sustainability of the PE Toolbox and tools are strategically linked. In close connection with task T6.4 *Sustainability of the PARADIGM outputs*, the PE Toolbox can be considered as the repository for the tools, but only the relevance and usability of the tools over time will make the toolbox itself valuable. The task T6.4 is *"devoted to ensuring that the main project outputs generated by the different WPs have a clearly defined sustainability plan that ensures their use by the community after the end of the project and contains the following detailed aspects:*

- *Recommendations/plans on how outputs might be sustained and made available, when and by whom,*
- *Further work necessary, if any,*
- *Potential/expected impact.*

*Special attention will be devoted to the Patient Engagement Open Forum (PEOF), which was positioned as a very welcome asset to gather and structure discussions within the PE community. Following discussions with the three powering initiatives of the PEOF, a set of recommendations will be developed on how to continue the PEOF (or similar) after the end of PARADIGM."*<sup>11</sup>

We propose that the entities which might agree to take up the organisation of the upcoming PEOFs, would be accountable for the financial sustainability of the PE Toolbox, ensuring continuity of the service and the conceptual linkage with the PEOF as the main, Europe-based global, disease and country agnostic event on patient engagement.

Due to the evident fast-evolving nature of the PE environment, the commitment to organise the PEOFs should not exceed 3-5 years, as it cannot be predicted what the future of PE will entail.

## **4. Limitations**

Firstly, the main limitation of the PE toolbox is the timeframe of PARADIGM, which on one hand allowed for the combined collective energy and commitment needed for the co-creation of the tools and the toolbox, and on the other hand brings the project to an end after 30 months. The sustainability of PARADIGM outputs (described in D6.4) post-PARADIGM will rely on the voluntary commitment of the PARADIGM partners, without foreseen resources, to continue PARADIGM related operations. However, the dissemination of the PARADIGM tools can be enhanced by other entities supporting the effort.

<sup>10</sup> <https://imi-paradigm.eu/project-partners/>

<sup>11</sup> IMI PARADIGM project Description of Action, amended in March 2020

Since the philosophy is not to generate profit, the nature of the commitment of the entities that would bear the financial risk would be voluntary and therefore subject to their goodwill and abilities. The current contingency strategy is to share the risks amongst the organisations that have co-organised the three PE Open Forums (years 2018-2020 under the PARADIGM grant agreement) and plan to organise the PEOF202X, which is described in deliverable D6.4<sup>12</sup>.

Secondly, a limitation exists in the on-going value of the PE toolbox, which is linked to the (current and future) relevance, uptake, usability and update of the tools in a continuously and fast evolving PE landscape. It is also worth noting that the PE Toolbox is of use only if users apply the tools stored in the PE Toolbox which is beyond the scope of the T4.3 and this deliverable.

Thirdly, the current continuation plan to make the PE Toolbox and tools accessible in the short term (3-5 years) that was agreed by two of the partners (The Synergist and EUPATI Foundation) can be jeopardised by the business continuity of the Synergist and the sustainability of the EUPATI Foundation. However, it should be mentioned that both the financial forecast and operational capabilities of the company as well as those for EUPATI are solid for the given timeframe.

Finally, it is acknowledged that a user testing round would have been necessary to fully ensure the usability of the PE Toolbox by all actors. However, time and resources did not allow the PE Toolbox developers to do so. Nonetheless, mitigating this shortcoming, the PE Toolbox will be presented at the PEOF2020 session on September 10<sup>th</sup>, people (more than 500 expected, out of 1300+ registered participants) coming from all the stakeholder groups will test during the session the PE Toolbox and will send feedback to the developers.

---

<sup>12</sup> For more information on the PARADIGM deliverable D6.4 Sustainability of the PARADIGM outputs <https://imi-paradigm.eu/resources/?categorie=104#resource-filter>