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# New EU Clinical Trials System Could Support Patient Recruitment

by Vibha Sharma

The EU research-based pharma industry is exploring partnerships to develop an app that would extract data from the new Clinical Trial Information System and convert it into lay format to guide patients interested in participating in studies.

The EU clinical trials portal, which is set to go live on 31 January 2022, is expected to usher in a new era of transparency, with vast amounts of clinical trial data being made public that may be put to new uses to benefit patients.

Drug companies are exploring if they can use some of this data to address one of the most challenging aspects of the drug development process – finding patients to participate in trials.

The new EU Clinical Trials Information System (CTIS) may be able to offer a solution on this front as it requires all sponsors to submit certain information about their studies in a specific format, said Zsófia Bakonyi of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Efforts are on to explore whether some of this publicly available information from the CTIS portal can be extracted to develop and support a new app/website on EU trials being run by industry and academic sponsors, said Bakonyi, who responsible for implementing EFPIA's patient engagement strategy and is senior manager of partnerships.

The app/website would be used by patients interested in participating in these trials, Bakonyi said at the Drug Information Association's annual conference on clinical trial disclosure & data transparency, which took place virtually from 29 November to 1 December.

As EFPIA cannot develop the clinical trial finder app/website on its own, Bakonyi said the trade body was still exploring collaborations. A prototype is expected to be ready in a year's time "if we

have the right partners," she said. It may, however, take up to five years to make the platform fully functional.

A senior official of the European Medicines Agency – which has developed CTIS and is responsible for its maintenance – said this was a welcome initiative. The EMA's purpose in making trusted clinical trial information public is to ensure that it can be "used and reused as much as possible" and the EFPIA initiative "goes in this direction," said the agency's Juan Garcia-Burgos, who also spoke at the conference.

The EMA would be "happy to help implement it," said Garcia-Burgos, who is head of public and stakeholder engagement at the agency.

While the EMA has championed efforts to promote clinical trial transparency over the last several years, Garcia-Burgos said a key problem faced by the agency was drawing public attention to its website. Although the EMA is "now more known because of the [COVID-19] pandemic, it is not as well known to the outside world," he added.

So any initiative "by which the information we have… can be promoted" was welcome, he said. On whether it would have been better had the initiative come from the EMA rather than from the pharmaceutical industry, Garcia-Burgos said this did not matter so long as there was clarity on the ownership of data.

"For me, this [initiative] is an exercise of promoting information," and "nothing changes" the fact that the "clinical trials database is owned by the EMA," he added. Bakonyi clarified that the idea for the initiative did not originally come from EFPIA, but from patients' organizations during discussions held with the industry group.

## Fragmented Trial Information For Patients

Bakonyi explained that problems around clinical trial recruitment have been an ongoing issue and this has prompted many companies to invest in their own clinical trial finder platforms over the years. However, "patients find this landscape quite fragmented," she said. Instead of being steered towards individual company websites, patients have indicated that they would instead prefer one common platform across all sponsors, covering academic and commercial studies.

The need for an EU-wide "clinical trial finder" was highlighted during interactions organized in 2018 by EFPIA's Patient Think Tank, which is a forum for patient organizations and industry to exchange ideas. The patients said they wanted one common searchable platform that should:

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  - Provide information only on actively recruiting trials, with the option to search studies

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taking place in the patient's geographical vicinity. Also, it should provide the location and contact information of investigator sites.

- Specify the study's therapeutic area, indication, inclusion and exclusion criteria, and a lay language description of the trial.
- Be fully smartphone compatible, easy to use and should contain information in most European languages.

As trial sponsors are required to submit all this information to CTIS, EFPIA decided that an app/website that can extract information from the portal would be the ideal solution. The app/website could either directly extract this information from CTIS data fields visible to the public or modify it using artificial intelligence to provide content to patients in lay language, said Bakonyi. (See Table 1)

Table. 1: From the fields available in the CTIS portal visible to the public, information highlighted in bold could be extracted into the clinical trial finder app/website.

| | |
|---|---|
| **EU clinical trial number and other information including public title** | **Endpoints (primary and secondary)** |
| **Condition** | Trial duration |
| **Sponsor** | **Population of trial subjects (age, gender, vulnerable population, etc)** |
| Trial Phase | Full protocol document |
| Therapeutic Area | **Protocol synopsis (in lay language)** |
| **EU member states concerned and trial status in member states** | **Study design** |
| **Population type** | **Products being tested** |
| **Main objectives** | **Clinical trial sites (organization name, street, city, postcode, country, department, phone number, etc)** |
| Secondary objective | Summary of product characteristics |
| **Eligibility criteria (principal inclusion and exclusion criteria)** | |

*Source: EFPIA/Drug Information Association*

For EFPIA, ensuring that the digital platform has a patient-friendly, intuitive interface is key. While existing clinical trial registries, such as clinicaltrials.gov and EudraCT (the EU clinical trials database), also have information on ongoing studies, one needs to be "fairly specialized" to understand what is in these registries, a conference participant remarked.

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EFPIA also wants the platform to be free and sustainable in the long term. The industry association is, however, not keen to be directly associated with the app/website as it recognizes that having a "neutral and trustworthy organization behind the platform would be extremely important," said Bakonyi.

For this, it is looking for support from the EMA and other collaborative organizations, such as Patient Focused Medicines Development (a global multistakeholder collaboration of health stakeholders) and the EU's Innovative Medicines Initiative (a public-private partnership to speed up medicines development).

"The platform needs to be sponsor-independent," and "money and a dedicated team" would be needed to run it, said Thomas Schindler, who is part of EFPIA's clinical trial transparency team. This means it would either be funded with public money or "we need to find some private money, which may come from industry," he added.