The experiences of pharmaceutical companies, study doctors and delivery couriers with delivering trial medication directly to participants in Europe

Acknowledgement & Disclaimer

This article is not an original, it has been translated by the Trials@Home Layman Translation Team for purpose of a better understanding by a general audience. The team consists of a diverse group of Trials@Home consortium members and the members of the Trials@Home Patient Expert Panel.

*Original paper - **Direct-to-Participant Investigational Medicinal Product Supply in Clinical Trials in Europe – Exploring the Experiences of Sponsors, Site Staff, and Couriers***

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What is this article about?

Direct delivery of the medication being tested (the trial medication) means that patients who participate in a clinical study get their study medication directly to their homes. Participants don't need to go to a clinic or hospital to receive the medication. It is necessary to better understand how this delivery should be done. There is no one set of rules on this in Europe. This article is about the pros and cons of delivering trial medication directly to participants, what is difficult, and what could make it easier.

The term "direct trial medication delivery to participants" will be abbreviated as "DtP" throughout the rest of the article. This stands for "direct-to-participant".

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458

What did the researchers do?

The researchers interviewed 16 people from pharmaceutical companies, courier delivery services and people who handle trial medications at hospitals and clinics in Europe. These people had experience with different ways of DtP shipping and storing trial medication. The interviews took place between May and November 2021 and the responses were analysed.

What did they find?

People who were interviewed said:

- DtP from a study site (a hospital, clinic or doctor's office running a clinical trial) can be time-consuming and complicated for the people working at the study site
- The easiest way to send trial medication was from a central storage location but there were concerns about data privacy and ensuring that the people doing this work followed the correct procedures.
- For trial medications that are already available to be prescribed, it can be useful to work with local pharmacies.

Conclusions: The researchers identified three options to provide trial medication directly to participants in Europe. This information can be useful for organisations trying to obtain permission to run a clinical trial with DtP.

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Introduction

To have new medications developed and approved, clinical trials are required. With new digital technologies now being easily available, it is now possible to run some clinical trials from the participant's home. This can be done via the internet or telephone without having to see a study doctor at a specific clinical trial site. These kinds of trials with limited face-to-face interactions are called "decentralised clinical trials" (DCTs). This type of clinical trial can be easier for participants, since trial medication is often delivered directly to them.
In the European Union (EU), European and country laws control how the trial is evaluated and thus also how trial medication is sent to participants.

Previously, researchers found that each European country has different rules on how to handle DtP in clinical trials, which can lead to different solutions for each country. Before the Covid-19 pandemic, DtP was not allowed in most European countries. When Covid-19 restrictions regarding travel and in-person contact were put in place, health authorities came up with instructions about how to deliver trial medication directly to patients. These instructions often stated it was acceptable to send trial medication directly to a participant's home rather than needing to pick it up at a clinical trial site. However, the exact steps were not the same in each country, and it's unclear whether there will be a universally agreed and enforced way of doing it in the future. This may lead to people running studies being cautious about sending trial medication directly to participants.

There is a need to learn more about how to use DtP so that the same rules can be developed and put in place in all European countries. This article describes the learnings on how different trials in Europe handled DtP before and during the Covid-19 pandemic. The article also looks at the advantages and disadvantages of DtP, what is difficult and what could make it easier.

What was known already prior to this research:

- ⇒ The rules for DtP are not the same across Europe.
- ⇒ Clinical trial participants usually need to visit a clinical trial site in person to pick up the trial medication.
- ⇒ DtP delivery of trial medication would make it possible to conduct trials without face-to-face interactions.

What the researchers found:

- ⇒ DtP from a study centre or a pharmacy is already being done in Europe and makes it easier for trial participants to take part in a clinical trial.
- ⇒ It is important to carefully think through all steps of the DtP process across various situations, including different kinds of patients, trial medications, differences in local rules and participant privacy

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What did the researchers do?

The researchers interviewed people from pharmaceutical companies, courier delivery services and people who handle medications in clinical trials in Europe.

What questions were asked?

The researchers decided on four main questions to ask the people being interviewed, based on what the researchers knew and had read about DtP:

1. What are your own experiences with DtP?
2. What was easy and what was difficult about this process?
3. What are your opinions on the advantages and disadvantages of different ways of DtP?
4. What would your recommendation be for DtP?

In collaboration with a DtP delivery expert, a final interview document was created, including additional questions about:

5. What are some ways pharmaceutical companies use to make it easier to work with hospital pharmacies for DtP?
6. What are your experiences with importing trial medications into different countries?

Table 1 in the original paper shows the interview guide in more detail.

Who was interviewed and how?

Between May and November 2021, the researchers interviewed 16 people online (of the 27 they invited). All the people interviewed had already used or were planning to use DtP in Europe before or during the COVID-19 pandemic. Eight of the people interviewed worked for a shipment courier service, five for pharmaceutical companies, two were hospital pharmacists and one was a researcher at a university. Table 2 in the research paper shows what their individual experiences with DtP trial medication delivery in Europe was. The people who were interviewed agreed verbally at the beginning of the interview.

How were the interviews analysed?

The interviews were audio-recorded and written down word-for-word. The researchers analysed the recordings to find common themes and ideas independently from one another, applying standard methods. The research team discussed these themes and ideas together, then organized and grouped them. After analysis, the people who were interviewed were given a written summary to confirm everything was understood and written down correctly.

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What were the results?
What common themes did they find?

When the researchers looked at what people said in the interviews, there were three main themes that they found: 1) how DtP trial medication delivery was done in Europe, 2) things that help with making DtP trial medication delivery easier and 3) the influence that rules and regulations have on the process.

How can trial medication be delivered in Europe?

- **Experiences**

Figure 1 in the original article shows different ways of how DtP can be done in Europe, according to what the people shared in the interviews. However, it should be noted that not everyone had the same definition of DtP.

The people who were interviewed described many different ways trial medication can be shipped to participants. Most people did this by having the study site send medication to the participant because this seems relatively easy. It was noted that, because pharmaceutical companies cannot have access to study participants' personal information, this limits the ability for them to ship it directly to the participant. As a result, a pharmacist will often need to be involved in the dispensing of the medication, via a prescription. In other cases, the delivery can be done through home nurses, by post, or by courier.

- **Pros and cons of the different ways of DtP**

Although DtP from the study site was the way with the least hurdles, it wasn't always easy for the site staff to manage it. Shipping the medication in a more centralised manner and using computer systems would make it easier and save money. This could help reduce waste of trial medication. However, when trial medication is shipped from a central location, the normal services provided by a nurse or pharmacist (like answering participants' questions) can't be provided as easily.

Read these four examples for how DtP was performed based on what the interviewees said during their interviews.

- **EXAMPLE 1: Nurse brings medication**

In a trial with cancer patients, the medication was given as an infusion (a liquid was slowly given directly into a vein through a tube and a needle). The trial medication was shipped directly to the participants by courier and a nurse visited the participants at home to do the intravenous infusion. However, if the participant lived near the study site, the nurse could pick up the medication before going to see the patient.

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- **EXAMPLE 2: Pharmacy sends medication by post**

This was a clinical trial where the medication was already available in pharmacies. This trial was run in the UK, Denmark and Sweden. In the UK and Demark, the trial medication was sent to participants directly by post from a single distribution centre (this is called a central pharmacy). In Sweden, the medication was sent from the central pharmacy to local pharmacies where the participants had to pick it up. It was possible to run this trial because it was relatively cheap to provide medication to participants this way.

- **EXAMPLE 3: Study site ships medication by courier**

This trial was on a medication that had to be refrigerated. It was shipped to participants from the study site. Each of the five participating countries had a study site from which couriers collected the medication for delivery to the participants' homes. This process was complicated for participants due to the relatively large size of the package and the need for refrigeration, requiring multiple smaller shipments.

- **EXAMPLE 4: Patient picks up medication at local pharmacy**

This study, organised by a hospital, investigated an already publicly available injectable antibiotic for a condition it was not initially approved for. General practitioners were also involved in inviting patients to participate in the trial, and local pharmacists provided the trial medication to the participants. Since the medication was already available, the DtP process was simplified during this trial.

Not all DtP models can be used for all types of trial medication. There are some aspects that could make it difficult or impossible to do this, like how the medication needs to be stored, its side effects and risks, how it needs to be prepared, how it is given to participants, etc. This should be considered when you want to use DtP. It’s easier to send trial medication directly to patients when it is already approved for public use.

One hospital pharmacist talked about how there are changes planned to the European trial regulations that could make it easier for certain trial medications to be picked up with a prescription at a local pharmacy.

- **Advantages and disadvantages of the different delivery methods**

Although it’s a popular option to ship study medication via post because it’s less expensive, this can be problematic because you can’t prove that the medication was delivered to the actual trial participant, especially for medications like, for instance, strong painkillers.

Another concern is that you can’t track where the shipment is or prove that it has arrived. People who work for courier services have said that it can make it easier for participants if delivery can be flexible and, for example, be made to the participant’s workplace. However,

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using a courier service is more expensive and trickier to organize, which several people who were interviewed have said.

- **Shipping directly from participants**

Some trials may require that participants ship things like unused trial medication or blood, urine or other samples back so that they can be accounted for or analysed. People who were interviewed said that unused and empty trial medication packages are normally sent to study site pharmacies where they can be checked, documented and destroyed. This can be done in a similar way as shipping medication directly to participants, like with postal mail or courier services. However, a hospital pharmacist said that participants aren't always motivated enough to send unused medication back through postal mail, which can make it difficult to confirm that the study participant took the medication the way they were supposed to.

- **What has helped making DtP trial medication delivery more acceptable?**

Some people who were interviewed said they never used DtP before the Covid-19 pandemic. They mentioned that the pandemic has helped in making this more acceptable because it made it possible for people to keep participating in clinical trials. People who worked for courier and for pharmaceutical companies suggested that the Covid-19 pandemic could change the way future clinical trials are run. However, one hospital pharmacist reported that, after the initial Covid-19 outbreaks, trial medication was no longer shipped directly to participants but once again had to be collected at the study site.

- **Patient-friendliness and engaging with patients**

Most people who were interviewed agreed that both the shipment of trial medication directly to patients and the possibility to perform study activities from home makes a clinical trial more participant friendly. This can also make it less expensive because there are no travel costs or accessibility issues. Some participants can also find in-person visits stressful. Many of the interviewed people also said that DtP could make participants more willing to join and stay in a clinical trial, especially if they don't live very close to any of the study sites.

This was especially important for long-running trials that don't have a lot of medical procedures at the study visits. Even though this may be more difficult to organise, it was recommended to let trial participants choose whether they prefer to have trial medication sent to their homes or whether they want to pick it up at the study site. People working for pharmaceutical companies said that, after hearing feedback from trial participants, it is generally well received to have trial medication sent to their homes, although there may be cultural differences. It was explained that it's important to involve and listen to patients when a clinical trial is designed to try and address the participants' needs. You shouldn't make assumptions about what patients want, you should ask what the patients actually like or don't like or what they think could make a clinical trial easier or more challenging for them.

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How do rules and regulations affect the process?

- **Differing rules**

The fact that there is not a single set of rules on how to handle and manage DtP is seen as one of the hurdles to use this approach. The rules and regulations that are in place for DtP, home nurse visits and importing and handing out trial medication are different from country to country. It takes a lot of time to organize trial medication shipments from one country to another. This means that decisions for DtP must be considered for each trial.

A person working for a courier service said that, even though the courier can give information to companies about what is possible and what isn't, the company can decide not to use DtP because it doesn't fit with that particular clinical trial. The courier service cannot generally say what is allowed and what isn't because every clinical trial is different.

Some people said that it can help not to have very clear rules and regulations because it can then be decided one at a time if DtP is possible on a clinical trial. It can be helpful not to put too detailed information into the study protocol (the official document that outlines how the clinical trial is set up and run) how trial medication will be provided to participants in the different countries. However, this contradicted what some others have said, namely that it is needed to be specific about how trial medication is provided to participants in order to get permission from the authorities to run the clinical trial.

One person commented that sometimes it happens that rules aren't applied in the same manner when you provide trial medication directly to participants. Some trial medication needs to be stored at certain temperatures (e.g. refrigerated), which a courier would also have to ensure during the time the medication is transported to the participant, but that this isn't being checked or kept track of when trial participants pick up the medication in person and transport it home.

- **Privacy**

Data privacy rules and regulations came up often in the interviews. The rules used for shipping trial medication to the participant from a study site are not much different than those used for when the participant goes to the study site in person. Data privacy rules become more important when companies who run the trial get involved in shipping the medication to participants. There are regulations in place that say that the company who runs and finances the trial should not have access to the trial participants' personal data and that personal data should only be used to ship the trial medication to the participant. Courier services should only be given the minimum amount of data they need in order to deliver the trial medication and confirm the identity of the recipient. One example was that the full name and the date of birth should not be put on the parcel label.

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In addition, the patient information and consent document that participants receive at the beginning of the trial, and that they need to sign, should contain all the necessary information about the trial medication shipping. The success of DtP for a clinical trial depends on how well data privacy is controlled to make sure people involved in the process are only given the data that they need.

People working for a courier service said that they need enough data so that they can do the following:

⇒ Be able to deliver the trial medication to the participant or someone else the participant gave permission to receive it.

⇒ Contact the participant before the delivery to agree a time and place for the delivery.

⇒ Return the shipment to the sender if it cannot be delivered to the trial participant.

- **Supervision by the doctor conducting the study**

According to rules and regulations for clinical trials, the doctors conducting the study are responsible for how trial medication is handed out, returned, tracked and documented. They can grant permission to other people to do this on their behalf, for instance a courier service or a central or local pharmacy. The doctors are also responsible for the safety of the study participant. Although most doctors are willing to accept that trial medication is sent directly to participants, some of them have been hesitant or unwilling to give other people permission to handle this on their behalf. This could be because the doctors don't fully trust others to do it properly because ultimately, they hold the responsibility, or the doctors may prefer to do it themselves. A good solution to increase confidence in DtP could be to let the study site staff play an active role in the process or to let study sites choose whether they want to use DtP or not.

What have we learned?

The researchers listened to the experiences with DtP in clinical trials in Europe and how it can be done. The people who were interviewed for this paper suggested that the Covid-19 pandemic and the need for clinical trials to be more participant-friendly are the most important reasons why it's become easier to use DtP in clinical trials. One of the hurdles for DtP is that there are no universally agreed rules and regulations on how it should be done, but that may also be a positive because it can be decided one at a time how to use it in clinical trials.

- **Experience with DtP**

DtP has been used on several different clinical trials in the past. The results of this paper are similar to what other papers have also shown, which is that DtP can have advantages for the following reasons:

⇒ It can reach people across widespread areas.

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- ⇒ It can make clinical trials more convenient for participants in their daily lives.
- ⇒ It can help with managing or running clinical trials from a central location.
- ⇒ It can reduce the need for participants to physically go to a study site or a pick-up location, which helped when people were quarantined during the Covid-19 pandemic.
- ⇒ It can help with making it possible for more patients and also more doctors to take part in clinical trials.
- ⇒ It can make a clinical trial less work for the staff at the study site.
- ⇒ It can make it easier for participants to continue taking their medications as instructed.

Even though DtP has been used on a number of different trials in different phases of clinical research, it might not be possible to use this method for all types of trial medication because of factors like unknown side effects and risks, a more involved or complex way of giving the medication or the need to keep the medication refrigerated. As an example, there was a paper that found that DtP was mostly used in trials with oral medications (e.g. capsules, tablets) that were already on the market for public use.

What also plays an important role is whether the country has courier services that can deliver the medication or central pharmacies that can ship them. The researchers have found that the most common way in Europe for sending trial medication to participants is shipping from a study site to the participant directly because the rules and regulations for this are fairly easy to follow. It is also very similar to what is done in a traditional clinical trial (going to the study site for study visits). Doctors conducting the trial might be more comfortable with this method.

Additionally, the rules and regulations state that the doctors are responsible for handling and documenting what happens with the trial medication, but they may grant permission to someone else to take this over on their behalf. This can cause some concerns for the doctors because they might not be comfortable with letting someone else who doesn't work for the study site handle the shipment of the trial medication.

Some people who were interviewed said that they had no experience with DtP directly from the pharmaceutical company who is running the study to participants in the EU because of issues with data privacy (pharmaceutical companies are not allowed to know the identity of trial participants) and because of certain DtP rules that include pharmacies. One possible solution is having pharmacists who work for the company running the study distribute the trial medication, but privacy issues might still exist. Another option is for participants to visit the study site initially, with later supplies sent directly to them. Involving a home health nurse is also an option, though it might be more expensive and less efficient.

- **Better defining the different ways of DtP**

The researchers found that the different ways of how to directly deliver trial medication to participants are not defined very well. It's also not very clearly defined which parts of the trial

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medication delivery process the study doctor is allowed to let other people do on their behalf. When a company who runs a study decides to use DtP to participants, the following things related to responsibilities for the medication handling may change:

- ⇒ The company chooses a specific pharmacy and their processes rather than the study doctor using their preferred pharmacy.
- ⇒ A delivery courier has more direct contact with trial participants.
- ⇒ The trial participant has to take a more active role in managing and documenting the use of the trial medication.

Therefore, the researchers recommend that more details about DtP are added to official guidance documents from the medical authorities and that more people share their own experiences and recommendations in scientific publications, knowing that there are many different ways out there how DtP can be done.

The researchers have found the following four main ways of direct trial medication delivery:

- ⇒ From the study site to the participant
- ⇒ From a central pharmacy to the participant
- ⇒ From a local pharmacy to the participant
- ⇒ From the company running the study to the participant

The results described in this paper suggest that the description of the method for how trial medication is being provided directly to participants should include:

- ⇒ From where the medication is shipped and whether or not a pharmacist is involved
- ⇒ The way that the medication is shipped
- ⇒ Who can see the personal data of the participant

When DtP is planned to be used on a clinical trial, at least three of these elements should be described in the overall study plan (study protocol) or in the plans that describe trial medication handling so that the medical authorities or other official review boards can say whether they find it acceptable or not.

- **Rules and regulations for sending trial medication directly to participants**

In Europe, every country has different rules and regulations for DtP. How you organise the delivery depends on the known side effects and risks of the medication and how stable it is at different temperatures. Because of these differences and to avoid delays, the companies who run clinical trials may prefer to run them in countries where they know their preferred method of DtP is permitted.

That said, the Covid-19 pandemic has helped to make direct delivery of trial medication more acceptable and has made medical authorities be more accepting of it as well. All the examples and experiences people have had during the pandemic have created a starting point from which medical authorities can continue changing the rules and regulations for direct trial medication delivery to create something more robust. Still, one hospital

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pharmacist has said that, after the pandemic, some study sites have gone back to only providing trial medication in person at the study site. This could mean that it's not being seen as overly beneficial to ship medication directly to participants, especially if this was only done out of Covid-19 necessity and wasn't really planned at the beginning to do it that way.

Recently, a European recommendation paper and national guidelines were published that made proposals related to what trial activities participants can do at home, which includes having study medication shipped directly to them.
Common themes in these publications include the following:

- ⇒ The study doctor is responsible for providing the medication to participants.
- ⇒ Participants need to be well informed beforehand about everything that is involved (including the data privacy).
- ⇒ The medication needs to be able to be shipped safely (including the side effects and risks of the medication and other important things like temperature control of the medication or how the shipment and storage is tracked and documented).

The European recommendation paper included a list at the end summarizing the different rules and regulations for DtP in the different countries. This list showed that most EU countries allow DtP from the study site or a pharmacy connected to the study site to the participant. Several EU countries also allow trial medication to be shipped from a central pharmacy or a local pharmacy. Only a few countries allow that the medication is shipped directly from the company running the trial or the trial medication manufacturer to the participant. Some countries are currently working on creating or updating their rules and regulations on this topic.

As per new EU rules and regulations, clinical trials that aren't very complicated and use already publicly available drugs have less requirements, which may make it easier to use DtP. For such trials, it may be allowed to use a local pharmacy to provide trial medication to participants. Nevertheless, the people interviewed for this paper said that it can be difficult to train all the people working at a local pharmacy to handle necessary trial documentation correctly. One group of trials used 130 community pharmacies and trained over 2500 pharmacy staff to handle trial medication, proving that this can be done at scale.

However, there were some difficulties:

- ⇒ working with other people and independent pharmacies that had to be authorized
- ⇒ staff at the pharmacies changing
- ⇒ rules of the local pharmacies that had to be followed in addition to the trial rules

It has been asked if such strict additional training of qualified pharmacists is needed.

- **Positives, negatives and suggestions for future research**

In this paper, the researchers looked at examples of DtP used in clinical trials in Europe. They were able to interview several different people, including hospital pharmacists, people

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working for pharmaceutical companies and shipping couriers who had experience with this kind of work in Europe and worldwide. This makes the researchers confident that their results are meaningful. They did recognize that they didn't interview a lot of study doctors or people working for study sites, which could mean that their views aren't well represented in this article. What the researchers found out is that it's possible to use different ways of DtP in clinical trials in Europe. Their results could also help to discuss DtP shipping with the medical authorities and review boards. The results could also be helpful for finding out what the best ways are to send trial medication directly to participants. The interviews for this research mainly focused on how the shipments worked in practice and how accepted the different ways of shipping were.

However, there are other things that should be considered. For example, if participants are okay with receiving trial medication directly, because this may be different in certain patient groups or in certain cultures. Some of the examples that were looked at for this paper didn't have very detailed information, which makes it harder to draw certain conclusions, possibly because interviewees aren't always comfortable sharing detailed information. The researchers hope that more papers and publications will be published in the future that speak to DtP to learn more about how feasible and accepted it is. The researchers also think it's necessary to hear and study more real-life examples and data on how to deliver trial medication directly to participants.

For example, it would be interesting to find out if DtP affects how well trial participants follow their medication schedules and how well the medication handling is documented. It would also be useful to have more information on how much direct trial medication delivery is accepted by both patients and study doctors.

In summary

In Europe, you can deliver clinical trial medication directly to trial participants, provided that the medication is suitable for it. That said, this way of providing trial medication could be more difficult for people working at the study site.

Regulations can affect the way that central and local pharmacies send trial medication directly to participants, because they are not universally accepted in the different countries. Study doctors may also be reluctant to let other people handle the trial medication that they are ultimately responsible for. For trials with medications that are already publicly available, it appears that the best way to deliver study mediation directly to participants is via local pharmacies. Clinical trials done on medications that are already on the market should consider using DtP.

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