# Maintaining access to clinical trials during COVID-19 pandemic

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## Introduction

The COVID-19 pandemic has affected the operation of clinical trials. Varying restrictions put in place by different countries, including lockdowns, curfews and cancellations of flights have made attendance at clinical trial sites for treatment and vital follow-up more difficult, but no less necessary.

The considerable burden to those participating in clinical trials has increased during the pandemic. With particular concerns over those with impaired immune systems and the need to balance requirements to self-isolate following travel, with other commitments.

To this end we have reviewed challenges experienced and additional steps taken during March to October 2020 to support and reassure patients we support, and their families who are affected by Battens, MPSII, MPSIIIA, MPSIIIB, Fabry or MLD.

| | |
|---|---|
| 1 | Monitoring of local and international travel restrictions |
| 2 | Contacting government health departments for up-to-date advice. |
| 3 | Consulting with airports and airlines to ensure travel requirements for passengers are understood and acted upon. |
| 4 | Providing/helping to obtain the correct travel documentation including exemption certificates and attestations. |
| 5 | Assisting patients/their families to source COVID tests before travelling, where necessary |
| 6 | Checking taxi companies and hotels have protocols in place to reduce the chance of infections. |
| 7 | Working with taxi companies and hotels to ensure their guidelines are understood and adhered to by patients/their families. |
| 8 | Where restrictions made travelling unfeasible, either relocating patients/their families near to clinical trial sites or assisting with arrangements to local hospitals, to ensure continued treatment and follow up. |

**Table 1 Additional support required due to COVID-19**

During this time, 75 patients were affected by travel restrictions to varying degrees, 323 changes were made, 3 people had to stop or pause their participation in a clinical trial as necessary changes could not be made. Their review demonstrates that even during a global pandemic, the right support and care make it possible for patients to continue to participate in clinical trials.

## Aims

**To determine if it is possible for patients with rare diseases to continue with treatment during a pandemic, and if so, the kind of additional support required.**

## Methods

An audit of patients supported by a rare disease clinical trial support service was conducted in November 2020.

The audit considered arrangements made for patients pre-COVID versus during the pandemic.

200 patients, over 21 sites and six diseases were reviewed. While the vast majority of patients will have seen some change to their study visits, such as the requirement to wear masks, this audit has focussed on where the service have had to intervene directly to some degree.

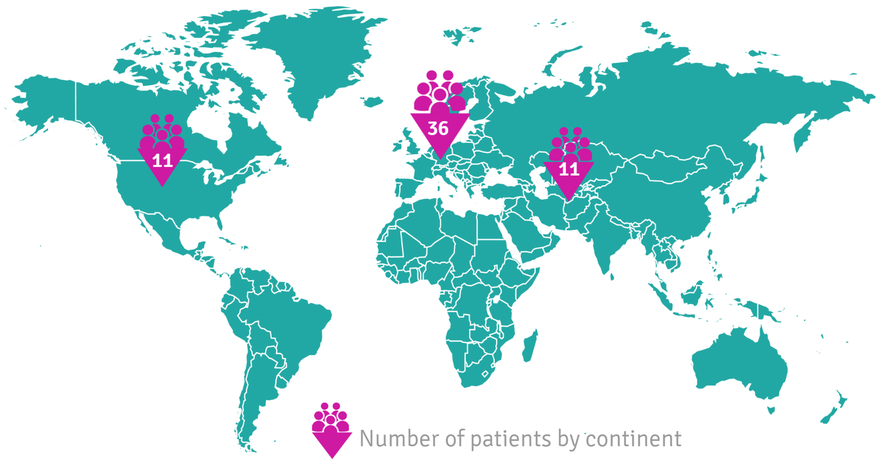


**Figure 1. Patient by continent**

A range of additional support was required (see Table 1), the spread of which can be seen in Figure 2 (below). 'Additional support' refers to supplementary actions required due to COVID-19 that were carried out over and above the usual support provided for the patients/their families.

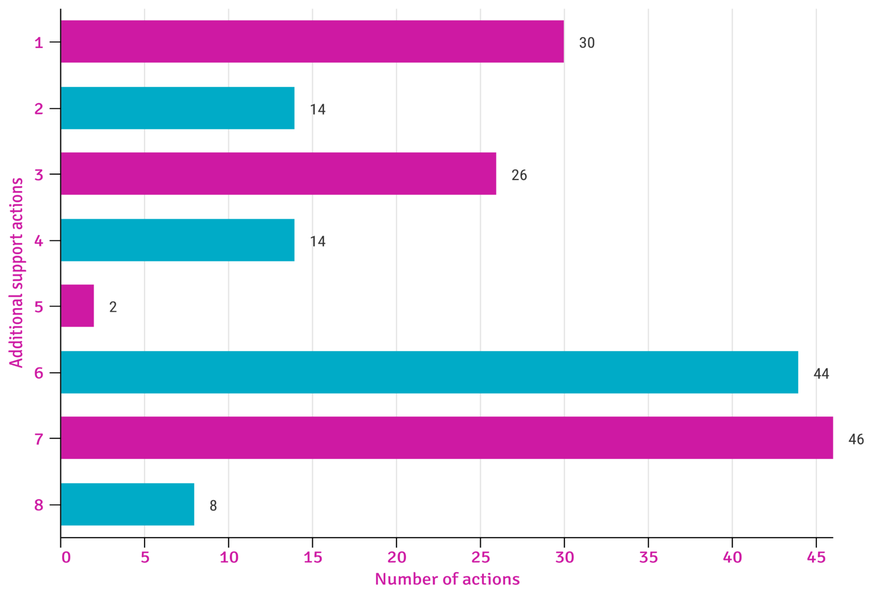


**Figure 2. Additional assistance provided during COVID-19 pandemic**

## Disclaimer

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## Results

The service provided additional support to 59 patients across three continents (Figure 1) across the six following diseases: Battens, MPS II, MPS IIIA, MPS IIIB, MLD and Fabry (Table 2).

From the data gathered, it would appear that the top three areas where additional support was needed were in the monitoring of local and international travel restrictions, checking the COVID-19 policies put in place by taxi companies and hotels, and communicating these requirements to the patients/their families.

The requirement to relocate patients/their families to the clinical trial site or to assist with travel to a local travel to a temporary site was also required but to a lesser extent than other areas of additional support.

| Rare Disease | Patients requiring additional support during Covid-19 |
|---|---|
| Batten Disease | 5 |
| MPSII | 2 |
| MPS IIIA | 11 |
| MPS IIIB | 17 |
| Fabry | 15 |
| MLD | 9 |

**Table 2. Spread of patients by disease**

## Conclusion

Overall, this audit highlighted the additional support required for patients to enable them to continue attending their study visits and receive treatment throughout the first 11 months of the COVID-19 pandemic.

While some patients were able to receive home care or temporarily have follow up visits at a hospital local to them, many patients did not have this option. Unsurprisingly, there was widespread travel disruption and in some cases, even if the patient was permitted to fly, there was not always a suitable flight available that didn't require two or more stopovers.

Despite this, the service was able to work with Sponsors to find either alternative methods of transport or to relocate patients to near the clinical trial site where necessary. By doing this and by providing the additional support outlined in Table 1, patients were able to continue treatment and provide valuable data toward the development of new treatments for rare diseases.