Balancing trial safety with Covid safety: Developing a drug-device combination for Parkinson's disease in CoViD times

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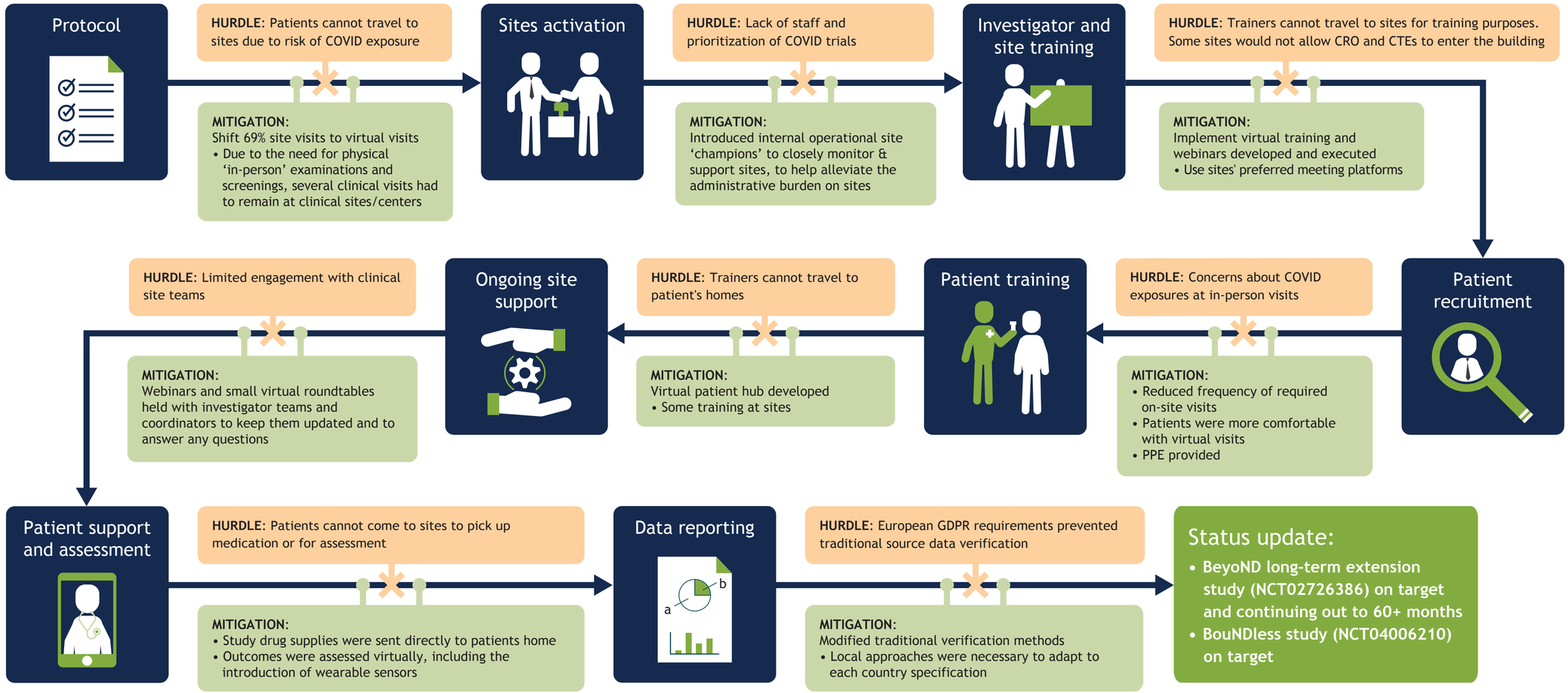
Introduction

- The COVID-19 pandemic had immediate implications for all global clinical trial operations.
- ND0612 is a continuous, subcutaneous levodopa/carbidopa delivery system in development for patients with PD experiencing motor fluctuations.
- In this vulnerable population, clinical trials investigating drug-device combinations typically involve several hours of in-person training and extensive support.
- Here we describe the hurdles of developing a drug-device combination for people with PD during the COVID 19 pandemic.

Conclusions

- Successful continuation of the two trials was dependent on maintaining close relationships and innovatively supporting the study sites.
- Telemedicine for training purposes was welcomed by the patients, but many preferred the in-person visits for continuity of care.

Impact of COVID 19 on ND0612 clinical trial operations



CRO: Clinical Research Organization, CTE: Clinical Trial Educator, PPE: Personal Protective Equipment