This study validated that the EMPAVELI® wearable injector can be used safely and effectively by intended users, including patients, caregivers, and HCPs, for prespecified utilizations in the expected settings.

The results show that the EMPAVELI® wearable injector can be used safely and effectively by intended users, including patients, caregivers, and HCPs, for prespecified utilizations in the expected settings.

CONCLUSIONS

- The study validated that the EMPAVELI® wearable injector can be used safely and effectively by intended users, including patients, caregivers, and HCPs, for prespecified utilizations in the expected settings.

- Qualitative findings from in-depth interviews of patients with PNH who help patients, caregivers, and HCPs, for prespecified utilizations in the expected settings.

- Among patients and caregivers, “Study limitation” and “Lapse” were the most common root cause categories.

- Overall, 29.3% and 29.3% errors were identified, of which the most common root cause categories were “Study limitation” and “Lapse”.

- Participants placed the injection pad and device on themselves, or not at all, which could cause harm including compromising the nature of the injection.

- The one HCP who failed the use test committed 6 of 10 possible critical use errors, of which the most common root cause categories were “Study limitation” and “Lapse”.

- The residual risks posed by the potential use errors were deemed acceptable (i.e., the benefits of the injector outweighed the risk).