Background

From 2017 to 2022 the oncology community has seen a significant increase in the number of cell therapy clinical trials in both hematologic malignancies and solid tumors. With breakthrough designations, priority reviews and orphan drug status, cell therapy regulatory approvals in hematologic malignancies have also significantly increased during this time based on acceptable safety/tolerability and positive clinical efficacy data from single-arm studies with relatively small sample sizes. As a global CRO, PPD has gained a wealth of experience in the management of these complex cell therapy trials in hematologic malignancies and solid tumors. Project teams managing these complex trials are supported by our Immuno-Oncology Cell and Gene Therapy Center of Excellence which provides a platform for sharing of knowledge and best practices as well as comprehensive cell therapy training. Through these cross-functional monthly meetings we review safety/tolerability between the different genetically modified cell therapies as well as those that are not genetically modified. We can also identify gaps in the management of cell therapy trials that could impact study timelines and create enrollment challenges. We demonstrate our comprehensive analysis of factors that could impact enrollment into our cell therapy trials and describe proposed solutions.

Methods

We reviewed cell therapy approvals in relapsed/refractory DLBCL from 2017 to 2022 and the changing treatment options that could impact enrollment into current and future clinical trials using the IPSOS prescribing database. The Citeline-Trialtrove study database was then used to assess the number of studies competing for the same patient population.

Results

From this evaluation we identified multiple factors that could impact enrollment requiring mitigation strategies to be implemented to prevent delays to study timelines (figure 8,9).

Conclusions

By using a combination of experiential metrics and publicly available data, it is possible to identify remediable factors which could negatively impact enrollment. Rapid implementation of targeted measures can improve enrollment and keep study timelines on track (figure 9).