

THAW–The Holistic Approach for Working in Cellular and Gene Therapy Clinical Trials

By Julia Gould, BA, Kayla Shrestha, MS, Rachel McCray, BS, Fran Brogan, MSN, RN, Daniel Otap, CCRP, Moshe Kelsen, MBA, Markus Mapara, MD, PhD, Ran Reshef, MD, Andrew Lassman, MD, MS

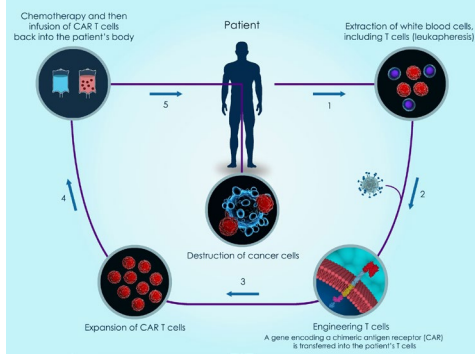
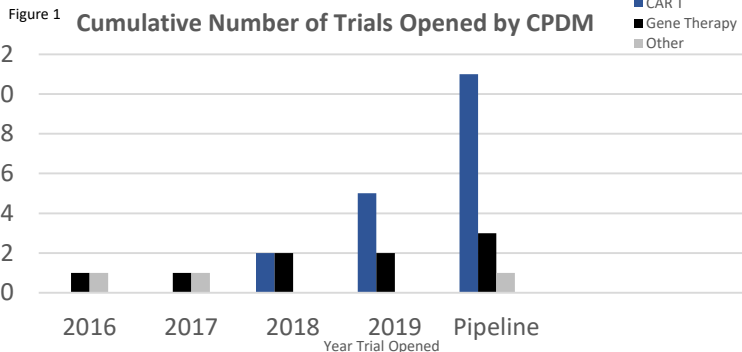


Photo obtained from Columbia Cancer Facebook page 2010UN2019.

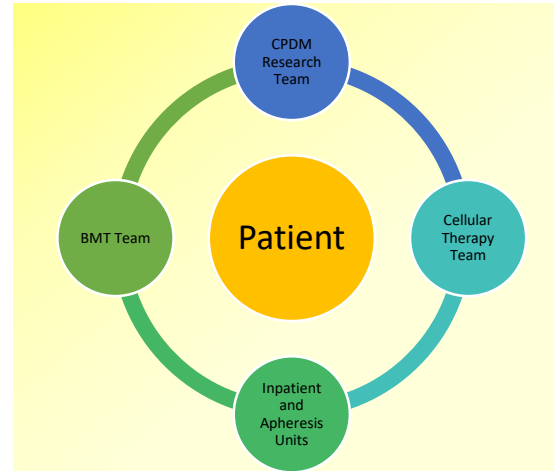
Background

Execution of cellular and gene therapy trials is highly complex and requires multidisciplinary interactions (cell therapy/transplant program, transfusion medicine, oncologic sub-disciplines, inpatient and outpatient patient care units) for which the research team is the core. The rapidly growing number of clinical trials in this area and their diversity across hematologic and solid tumor indications are some of the challenges that face an organization that wishes to operate in this innovative field. The Clinical Protocol and Data Management (CPDM) office began this cutting edge cancer and non-cancer research with its first gene therapy protocol in 2016. Since then, CPDM has developed a dedicated research team facilitating the execution of Cellular and Gene therapy protocols for varying indications from Sickle Cell to large cell carcinoma.



Methods

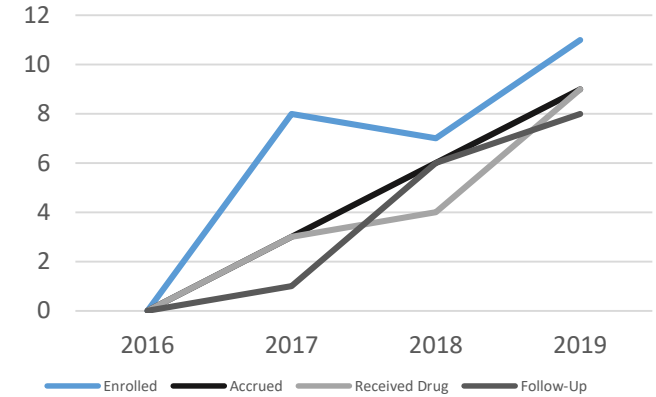
CPDM created a team dedicated to the cellular and gene therapy protocols. A senior CRC, a data coordinator, and a research nurse were assigned to supplement the efforts of the initial research nurses, CRC, and CRM. Detailed tracking mechanisms were implemented by the Clinical Research Manager to monitor all protocol processes from start-up through overall trial progress. Weekly meetings to review the tracker and protocol progress supplement the weekly disease team meetings. Furthermore, a departmental SOP outlining the roles and responsibilities when facilitating cellular and gene therapy clinical trials was developed. The SOP references supplemental workflow documents created to assist and reinforce trial procedures.



Results

Since its inception and implementation in 2016, 8 cellular therapy and gene therapy protocols have been opened, 28 patients have been enrolled, and 14 patients have been treated. With each enrollment, the study team continues to grow and assess the new processes set forth by the department.

Figure 2 Subject Progress from 2016 to Present



Conclusion

The implementation of the aforementioned processes streamlines communication, minimizes confusion, and provides structure for protocols with cross-departmental responsibilities. The processes are still in the beginning phases of execution. The cross-communication techniques will continue to be refined to ensure each subject's clinical trial experience goes as seamlessly as possible.

Next Steps

In anticipation of opening protocols with solid tumor disease origin, we anticipate doubling the numbers in Figure 1 and Figure 2 by the end of 2020.