03SEP2020 PACT Web Seminar - Q&A Session

The following questions were asked during the PACT web seminar Q&A session but were not able to be answered live during the web seminar. For other questions and answers, please listen to the audio recording posted on the PACT website.

1. **What's the best tracer that will enable quantitation of cell expansion (such as in the case for CAR-T)?**
   - There is no one best method however labels that do not dilute with expansion (such as Anti-CD8, [18F]FAraG) will enable longer qualitative/quantitative tracking.

2. **Even if we can locate specificity to where cells are after injection, what are best practices that the results will scale to human trials?**
   - Most of the probes discussed are already being used in clinical trials; if using these probes pre-clinically, scaling to human will not be an issue
   - If issue is body scale (animal vs human) - Gold particles in CT scans: can change concentration of gold particles

3. **Has the CT-TRACS group explored molecular methods for assessing the persistence and quantity of cells in patients, ex: ddPCR or sequencing methods?**
   - PCR methods are being used in clinical practice for liquid tumors (routine practice) and we have CT-TRACS members who have discussed and employ this method in preclinical studies.

4. **Given that probably the biggest Gate for novel treatments are Regulators. What is HESI doing to help stimulate dialogue and remove barriers for faster lanes for P1 and P2 studies.**
   - Regulators are included in the dialogue due to the multi-sector nature of the committee.
   - We are planning additional webinars and workshops to address regulatory issues.

5. **Can you image intracellular components using these in vivo tracking methods i.e mitochondria?**
   - To the best of our knowledge nothing is available clinically for that purpose.

6. **How do we ensure imaging probes do not alter the properties of the cells being administered and affect their efficacy?**
   - Many of the probes discussed have gone through a number of safety assessments before their application to human cells/subjects. Experiments to address this are often included as part of the pre-clinical workup and are included in regulatory filings for clinical use (ie - phenotype and functional experiments).