# Introduction

# On December 8, 2023, the Office of Clinical Trials (OCT) held its second annual retreat at the Johns Hopkins Carey Business School. Dr. Antony Rosen, Vice Dean for Research was our keynote speaker, while Drs. Max Konig, Assistant Professor in the Division of Rheumatology and Paul Brunetta, Senior Vice President of Clinical and Translational Science at Sana Biotechnology and Adjunct Associate Professor in the Pulmonary and Critical Care Division at University of California, San Francisco participated as invited guest speakers. Additionally, Drs. Sashank Reddy, Associate Professor of Plastic and Reconstructive Surgery, and Medical Director of Johns Hopkins Technology Venture and Steve Harr, President and Chief Executive Officer of Sana Biotechnology joined our invited speakers as panelist for an open discussion the role of academic medical centers in clinical development of novel therapeutics.

# Retreat Purpose and Format

The purpose of the OCT Retreat was to outline the strategic direction, priorities and achievements in research at JHM, to learn how research findings in the lab are translating into practical applications for patient care, to identify successful models of collaboration and potential areas for enhanced partnerships between JHM and industry partners, to recognize team strengths and challenges, explore new opportunities to assist research teams, articulate goals for next year to continue to make research easier for the research community and to build connections and foster collaboration within our teams and with outside partners.

We welcomed over 75 people from the Johns Hopkins School of Medicine, OCT, Institute for Clinical and Translational Research (ICTR), Office of Research Administration (ORA), and the Human Research Protection Program (HRPP). We featured invited guest speakers, conducted a panel discussion, and hosted small group exercises focused on SOAR analysis, which stands for Strengths, Opportunities, Aspirations, and Results.

# Presentations and Activities

Drs. Gail Daumit, Vice Dean of Clinical Investigation and Dr. Mark Sulkowski, Senior Associate Dean for Clinical Trials delivered welcoming remarks. After Dr. Sulkowski provided an overview of the OCT and highlighted its achievements in the past year, he introduced our keynote speaker, Dr. Antony Rosen, Vice Dean for Research.

Dr. Rosen challenged attendees to be courageous; he underscored that the world is continually evolving, emphasizing the need for academia to adapt and stay abreast of societal, technological, and economic changes. He urged us to embrace disruptive innovation because this will not only allow us to continue to fulfill our roles as drivers of knowledge creation, education, and societal progress but also remain competitive and prepare for the future. He mentioned that disruptive innovation necessitates courage, a commitment to action, a willingness to learn from mistakes, and a steadfast belief in our mission and vision, which is to lead clinical trials that push the boundaries of discovery for a healthier tomorrow and to support the Johns Hopkins community as a trusted gateway to clinical trials through customer-centric leadership, robust infrastructure, and harmonized processes.

Following Dr. Rosen’s inspiring remarks, our invited guest speaker discussed promising advances in the use of immune effector cells for the treatment of people with serious autoimmune diseases including systemic lupus erythematosus (SLE) form the academic and industry perspective. Dr. Max Konig, a practicing rheumatologist and physician-scientist, leads the Konig Lab in the Division of Rheumatology at Johns Hopkins. His team focuses on finding new ways to treat autoimmune rheumatic diseases and cancer, using autologous T cells genetically engineered to express a chimeric antigen receptor (CAR) that recognize the autoantigens causing disease. Dr. Koning discussed the recent and remarkable advances of Cellular Therapies for Lupus and other Autoimmune Diseases. The presentation was inspiring and meaningful, resonating with individuals who may not be physician scientists but play a crucial role in advancing science by providing support to investigators. The speaker adeptly translated complex scientific concepts into accessible language, making the potential impact of cellular therapies tangible. Dr. Konig demonstrated the importance of translating discoveries in the laboratory into the clinic where they have the potential to improve patient outcomes.

Following Dr. Konig, Dr. Paul Brunetta who is the Senior Vice President of Clinical and Translational Science at Sana Biotechnology and Adjunct Associate Professor in the Pulmonary and Critical Care Division at University of California, San Francisco, discussed the Cellular Therapies, using hypo-engineered cells for cancer, SLE, type 1 diabetes mellitus and​ other autoimmune diseases, from an industry perspective. Dr. Brunetta and other industry researchers share the belief that we are entering a new era of medicine marked by the capability to modify genes and utilize cells as medicines. This opens up new avenues for meaningfully altering the outcomes of various human diseases. However, it's crucial to acknowledge that this transformative potential comes with significant challenges that need to be addressed. The ability to modify genes and employ cell-based therapies brings exciting possibilities but requires careful consideration of ethical, safety, and regulatory aspects to ensure responsible and effective implementation. It's noteworthy to highlight the pivotal role played by the collective efforts of the Office of Clinical Trials to facilitate this work at Johns Hopkins, supporting faculty investigators and their research teams as they pursue groundbreaking clinical research.

Following the presentations, Dr. Sulkowski moderated a panel discussion featuring representatives from industry, Drs. Brunetta and Harr and academia, Drs. Konig and Reddy. The focus of the discussion revolved around the crucial importance of collaboration between industry and academia in the field of gene cell therapy. The dialogue emphasized how successful collaborations can accelerate advancements in medicine, leading to potential cures for our patients. The insights shared by panel members underscored the significance of bridging the gap between industry and academia, highlighting the synergies that arise when combining expertise from different sectors to drive innovation in gene and cell therapy.

After breaking for lunch, Marian De Backer, Director of the Office of Clinical Trials, facilitated small group action planning exercises using the SOAR analysis framework, encompassing Strengths, Opportunities, Aspirations, and Results. Each team lead within the group took on the responsibility of guiding their team to focus on identifying their strengths, leveraging opportunities, and generating meaningful results. The structured approach of SOAR aimed to bring out strategic insights that could enhance the effectiveness of the teams. Following the exercise, each group presented their findings with the retreat attendees, sharing insights derived from the SOAR analysis, fostering a collaborative environment for collective learning and improvement.

Dr. Sulkowski closed the retreat by thanking attendees for their enthusiastic participation and for their work to advance the Johns Hopkins discovery mission, serving our patients and researchers.

# Results of Activities

As highlighted by Dr. Rosen in his presentation on courage, an essential element to drive disruptive innovations, JHU SOM researchers aim to advance novel discoveries, directly benefiting our patients. Within the Office of Clinical Trials, we actively support the work of JHU faculty and their industry partners by accelerating clinical trial operations in our complex research ecosystem. For example, in the FY24 academic year, the OCT, in partnership with Research IT, is leading the implementation of OnCore, a clinical trial management system that streamlines processes, enhances financial efficiency, and improves the overall conduct of clinical trials. The benefits of OnCore include increased administrative simplicity, reduced costs through shorter startup times, improved accessibility via enhanced communication channels (websites, newsletters, emails), and greater customization, particularly in identifying and expediting high-priority trials such as CAR-T clinical trials for patients with autoimmune disease. Additionally, our commitment extends to supporting research faculty and staff. By simplifying and tracking clinical research operations, we aim to protect our core values and deliver value to our constituencies, ensuring that our efforts are consistently aligned with the needs and priorities of those we serve.

The outcome of the SOAR session was a success, with each group demonstrating a meticulous approach to identifying their distinctive strengths and strategically leveraging existing opportunities and formulating specific action plans for the upcoming year. The outcome is a collection of well-defined action plans that mirror the OCT's goal of streamlining clinical research operations and offering support to our research community.

# Conclusion

# The second annual OCT retreat achieved the objective of building effective teams to advance the translation of novel discoveries to our patients by partnering key stakeholders, including industry partners, to conduct clinical trials. The valuable in-person networking event also provided opportunities to meet and connect with colleagues, expanding collaborations and partnerships.

# Next Steps

The OCT will continue its commitment to being an excellent service organization, providing support to our faculty and staff engaged in clinical research. Our focus includes continuous efforts to enhance workflows and implement improvements, with a specific emphasis on implementing the new clinical trial management system.

