SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CIRCULATORY SYTEM DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE

February 13, 2024

9:00 a.m. EST

Webcast via Zoom

Attendees:

Temporary Voting Chairperson
Richard A. Lange, MD, MBA
President,
Texas Tech University Health Sciences Center
Dean, Paul L. Foster School of Medicine — El Paso, TX

Voting Members
James C. Blankenship, MD, MHCM, MACC, M-SCAI
Professor of Medicine, Director of Cardiac Catheterization Laboratory, and Director of Division of Cardiology,
University of New Mexico — Albuquerque, NM

Ralph G. Brindis, MD, MPH, MACC, FSCAI, FAHA
Clinical Professor of Medicine University of California, San Francisco — San Francisco, CA

Temporary Voting Members
Amit J. Shanker, MD, FACC, FHRS
Chair, Cardiovascular Service Line of St. Lawrence Health System,
Cardiovascular Medicine — Northern New York, NY

Amy M. Cizik, PhD, MPH
Research Assistant Professor, Department of Orthopedics, University of Utah School of Medicine — Salt Lake City, UT

Bradley A. Bart, MD, FACC
Professor of Medicine University of Minnesota School of Medicine
Staff Physician and Co-Director of Heart Failure Program,
Minneapolis VA Medical Center — Minneapolis, MN

Craig H. Selzman, MD
Professor and Chief, Division of Cardiothoracic Surgery,
University of Utah — Salt Lake City, UT

David A. Friedman, MD, FACC, FASE, FASNC, FACP
Cardiologist and Director of Heart Failure Program
West Carver Medical Group, Optum Tri-State/UnitedHealth Group Inc. — Huntington, NY

David D. Yuh, MD, FACS, FACC
Chair, Department of Surgery Stamford Hospital,
Stamford Health — Stamford, CT

John W. Hirshfeld, Jr., MD
Emeritus Professor of Medicine Perelman School of Medicine
University of Pennsylvania — Philadelphia, PA

Mitchell W. Krucoff, MD, FACC, FCCP, FAHA, FSCAI, FAPIC
Professor of Medicine, Director of Cardiovascular Devices Unit, Duke Clinical Research Institute — Duke University

Mladen I. Vidovich, MD, FACC, FSCAI
Professor of Medicine University of Illinois
Chief, Section of Cardiology Jesse Brown VA Medical Center — Chicago, IL

Paul J. Hauptman, MD, FHFSA
Dean and Professor of Medicine,
University of Nevada, Reno School of Medicine — Reno, NV

Scott R. Evans, PhD
Professor & Founding Chair Department of Biostatistics and Bioinformatics
Director, Biostatistics Center, George Washington University — Washington, DC

Industry Representative
Elijah Wreh, MS
Senior Regulatory Affairs Manager at Boston Scientific — LaGrange, OH

Consumer Representative
Rachel Brummert, MS
President of Courage to Continue, LLC
Communications Lead, American Society of Pharmacovigilance & Investigator of Charlotte-Mecklenburg Community Relations — Charlotte, NC

Patient Representative
Jennifer A. Schwartzott, MS
Founder/Program Manager MitoSantas — North Tonawanda, NY

Food and Drug Administration
Bram Zuckerman, MD
Director Office of Cardiovascular Devices, Office, CDRH — Silver Spring, MD

Designated Federal Officer
Akinola A. Awojope, MPH, DrPH.
Food and Drug Administration — Silver Spring, MD

CALL TO ORDER

Panel Chairperson Dr. Richard A Lange called the meeting to order at 9:00 a.m. He noted the presence of a quorum and stated that present members have received training in FDA device law and regulations. He stated the day's agenda and introduced the Panel Members.

CONFLICT OF INTEREST STATEMENT
TEMPORARY-NON-VOTING MEMBER STATUS STATEMENT
GENERAL ANNOUNCEMENTS

Akinola Awojope, Designated Federal Officer, reported that no conflict-of-interest waivers were issued. He announced that **Elijah Wreh** would serve as the Industry Representative and that **Bradley A. Bart, MD. Amy M. Cizik, PhD. Scott R. Evans, PhD. Dr. David A. Friedman, MD. Paul J. Hauptman, MD. John W. Hirshfeld, MD. Marc Katz, MD. Mitchell W. Krucoff, MD. Craig H. Selzman, MD. Amit J. Shanker, MD. Mladen Vidovich, MD. David Yuh** would serve as temporary voting members. And that **Richard A. Lange** will act as a temporary voting chairperson for the duration of this meeting

ABBOTT MEDICAL PRESENTATION

Dr. Sondergaard began the presentation by introducing himself as the chief medical officer at Abbott structural heart and discussed the need for a treatment for patients with severe tricuspid regurgitation (TR). He outlined the development of the TriClip device, which was based on Abbott's MitraClip technology, and described the TRILUMINATE trial, which evaluated the safety and efficacy of TriClip. **Dr. Adams**, the principal investigator for the TRILUMINATE study, discussed the unmet need for TR treatment and the trial design. He explained the trial's endpoints, patient demographics, and safety data, highlighting the low procedural risk and favorable safety profile of TriClip compared to surgery. **Dr. Sorajja** reviewed the clinical effectiveness data, including TR severity, patient outcomes, and health status improvements measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ). He emphasized the significant reduction in TR and improvement in health status with TriClip therapy. Overall, the presenters concluded that TriClip represents a significant advancement in the treatment of symptomatic severe TR, with a favorable benefit-risk profile.

Dr. Sorajja, along with **Dr. Adams**, served as a coprincipal investigator for the TRILUMINATE trial, focusing on a therapy for patients with TR. He highlighted the significant patient benefits observed in the trial, particularly with the TriClip system, which was both safe and effective in reducing TR severity. The trial demonstrated that TriClip patients had a substantial reduction in TR compared to control patients with sustained benefits observed up to one year. Furthermore, there were improvements in various health metrics, including the Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, physical functioning and symptom relief favoring the TriClip group. These improvements were consistent across different patient cohorts -- including the randomized and single-arm cohorts -- indicating the broad effectiveness of TriClip across various patient profiles. Additionally, physiological markers such as cardiac imaging and organ function showed favorable trends with TriClip treatment. Overall, the trial results supported the favorable benefit-risk profile of TriClip particularly considering the significant unmet medical need in patients with TR

Dr. Lurz, the Director of Cardiology at University Hospital Mainz, shared his perspective on TriClip therapy and highlighted its importance in treating patients with severe TR. He emphasized the evolution in understanding the significance of treating TR over the years

noting that TriClip has filled a critical gap in the field and provided a much-needed treatment option for patients. **Dr. Lurz** discussed the remarkable safety profile of TriClip supported by various studies and real-world data as well as its consistent effectiveness in reducing TR severity and improving patients' quality of life. He underscored the positive impact of TriClip on symptomatic relief and expressed gratitude for having this option to treat severely symptomatic patients. **Dr. Lurz** concluded by handing over to **Dr. Sondergaard**, who discussed ongoing post-approval commitments and emphasized the consistent efficacy findings across studies, endpoints and assessment measures supporting the value of TriClip for patients with limited treatment options.

QUESTIONS TO ABBOTT MEDICAL

Dr. Yuh inquired about the criteria used by surgeons to assess operative risk among patients. **Dr. Spinner**, the clinical program director at Abbott, explained that risk assessment was conducted by heart teams considering frailties and comorbidities, and most patients with TR seen in the clinic are high or intermediate risk. **Dr. Krucoff** raised questions regarding medication stability in the randomized cohort particularly concerning diuretics. **Dr. Benza**, a heart failure specialist, addressed this stating that patients were evaluated for ongoing medical therapy, ensured they were on goal-directed therapy for left-sided heart failure and adequately decompressed from right-sided congestion before entering the study. **Dr. Spinner** added that there were no changes in diuretic dosages observed from baseline to one year in the study.

Dr. Hauptman requested further clarification on the impact of mineralocorticoid receptor antagonists (MRAs) on the analyses. Specifically, he inquired about the potential effects on baseline comparisons and outcomes at one year as well as the possibility of conducting a responder analysis based on baseline diuretic use. **Dr. Spinner** deferred to **Dr. Benza**, who explained that virtually all patients were on loop diuretics at baseline, either alone or in combination with a thiazide or potassium-sparing diuretic, with minimal use of thiazide and potassium-sparing diuretics observed in the study.

Dr. Bart inquired about the rationale behind setting the treatment goals and specifically the 90% safety threshold and the 30% threshold for the single-arm cohort. **Dr. Shu** explained that the 90% safety goal for major adverse events (MAE) in the randomized controlled trial (RCT) cohort was based on literature data, with a presumed 4.3% rate of freedom from MAE derived from MitraClip studies. For the single-arm cohort, the 30% threshold for the primary endpoint was based on a 10% improvement in KCCQ scores and an assumed 25% mortality rate at 12 months.

Dr. Blankenship raised a question about why the improvement in KCCQ scores did not lead to fewer heart failure hospitalizations. **Dr. Adams** acknowledged that the understanding of heart failure hospitalization in the treatment group was still evolving and suggested that the one-year follow-up period might have been too short to observe significant changes. **Dr. Arnold**, a health services researcher, discussed the relationship between KCCQ scores and heart failure hospitalizations, noting that improvements in KCCQ scores at one month were associated with a reduction in the risk of subsequent death and heart failure hospitalizations among patients treated with TriClip.

During the Q&A session, **Dr. Brindis** asked about the percentage of patients excluded from TriClip treatment due to anatomical concerns. **Dr. Spinner** provided a breakdown, indicating that only 175 out of 1,409 patients were denied based on anatomical incompatibility, accounting for eight percent of the consented patients.

Dr. Selzman inquired about the relationship between the reduction in TR and KCCQ scores, particularly among patients with residual TR at one year. **Dr. Spinner** explained that the study was based on moderate or less TR but observed that greater reductions in TR generally correlated with more significant improvements in KCCQ scores.

Dr. Zuckerman raised questions regarding the placebo effect on KCCQ scores and requested a comprehensive overview of the physiological and biochemical parameters studied in the trial. **Dr. Cohen** addressed the placebo effect, suggesting that the observed improvements in KCCQ scores were larger and more sustained than what would typically be attributed to a placebo effect. He also discussed the relationship between the change in TR grade and the improvement in KCCQ scores, highlighting a significant correlation between the two variables.

Dr. Hauptman raised concerns about potential bias in the imaging sub-study selection process and its impact on the data interpretation. He questioned whether the patients included might have been biased towards those who were healthier and able to tolerate magnetic resonance imaging (MRI) and computed tomography (CT) studies. **Dr. Spinner** then deferred to **Dr. Cavalcante** to address these concerns.

Dr. Cavalcante clarified that the imaging sub-study deliberately included all patients, ensuring external validity by maintaining the same baseline characteristics as the main cohort. He highlighted that the TriClip not only reduced TR but also induced reverse remodeling of the right ventricle, as evidenced by quantitative analysis using cardiac MRI. Moreover, **Dr. Cavalcante** discussed improvements in pulmonary forward flow, contributing to enhanced right ventricular function. Regarding concerns about strain data, he explained that reductions in volume might lead to unfavorable changes in strain but emphasized the overall positive impact on right ventricular function. Lastly, he presented data illustrating the relationship between right ventricular reverse remodeling and improvement in KCCQ scores, indicating a favorable correlation.

Dr. Hauptman sought clarification on the exclusion criteria related to pacemaker or defibrillator leads that could hinder the placement of the TriClip device. **Dr. Spinner** explained that patients with leads were not automatically excluded but were assessed on a case-by-case basis by the anatomical eligibility committee. She noted that while some patients were excluded due to lead interference, a significant percentage with RV leads were still included in the study.

Dr. Hirshfeld raised a concern regarding the potential swapping of TR for tricuspid stenosis (TS) with the TriClip device, particularly noting the increase in mean diastolic gradient observed after TR reduction. **Dr. Sorajja** addressed this by emphasizing the balance between reducing TR and avoiding severe stenosis. He presented data showing that even in patients with higher gradients post-procedure, their quality of life significantly improved without evidence of stenosis-related complications.

Dr. Arnold referenced a study by Sneha et al. in heart failure, which showed a smaller improvement in the six-minute walk distance compared to the Spertus et al. paper, indicating that the correlation between KCCQ change and six-minute walk distance varies depending on the patient population and study design. She emphasized that while larger improvements were observed in specific quality of life domains like social limitations, these domains encompassed specific activities affected by heart failure, not just mental health. **Dr. Spinner** added that their data also demonstrated an improvement in six-minute walk distance among patients with significant KCCQ improvement, further supporting the relationship between these two measures.

FDA PRESENTATION

Megan Naber from the FDA presented an overview of Abbott Medical's pre-market approval (PMA) application for the TriClip G4 system. TR occurs when valve leaflets fail to close completely during systole, leading to blood regurgitation. TR can be primary, secondary, or induced by cardiac implantable electronic devices (CIEDs). Diagnosis and severity assessment rely on transthoracic echocardiography (TTE). TR is associated with various symptoms and decreased survival rates, particularly in severe cases. Current treatment options include medical therapy and tricuspid valve surgery, but there's an unmet need for patients who are refractory to medical therapy and not surgical candidates. The TriClip G4 system aims to address this need through minimally invasive transcatheter procedures. The device received Breakthrough Device Designation from the FDA, expediting its development and review process. The TRILUMINATE Pivotal Trial assessed the device's effectiveness, with the primary endpoint being the change in the KCCQ score, a patient-reported outcome. The trial's design included both randomized and single-arm cohorts. The FDA's presentation also covered non-clinical testing, regulatory milestones, the Breakthrough Devices Program, and statistical analysis methods.

Dr. Ye, the statistical reviewer for the TriClip G4 system PMA submission, discussed the study design and analysis methods. For the randomized cohort, the primary endpoint was a hierarchical composite consisting of time to all-cause death or tricuspid valve surgery, number of heart failure hospitalizations, and improvement in KCCQ score by at least 15 points versus baseline. The Finkelstein-Schoenfeld test method was used for hypothesis testing, with an adaptive design and a minimum sample size of 350 patients. A supplemental analysis included all 570 available randomized patients. **Dr. Ye** explained the methodology of the Finkelstein-Schoenfeld test, a nonparametric test based on pairwise comparisons. Additionally, win ratio analysis was performed as a supplementary method to estimate the odds of a better outcome in the treatment group.

For the single arm cohort trial, the primary endpoint was survival at 12 months and KCCQ score improvement by at least 10 points versus baseline. The hypothesis test was conducted using the exact test for binomial distribution with a one-sided alpha of 0.025, with an interim analysis planned after the first 100 enrolled patients completed 12 months follow-up. The study's success could be claimed if the test was successful at interim, with a sample size of 100.

Dr. Moscucci, from the FDA Office of Cardiovascular Devices, presented findings from the TRILUMINATE study, focusing on patients with severe TR at high risk for surgery. Enrollment spanned from August 2019 to June 2022, with 936 patients across 75 sites in the US, Canada, and Europe. The primary analysis included the first 350 randomized patients and 100 single-arm patients.

Patients were predominantly Caucasian, aged 78-80, with atrial fibrillation being the most common comorbidity. Nearly all had severe TR, and the TriClip device was successfully implanted in over 98% of cases. The primary endpoint, driven by improved KCCQ scores, was met in the randomized cohort, but there were differences in heart failure hospitalization rates.

The single-arm cohort also met its primary endpoint, with a notable improvement in KCCQ scores. However, adverse event rates were higher in this group. Limitations included the small sample size and open-label design prompting questions about generalizability and emphasizing the need for rigorous training. Overall, the study showed positive outcomes in technical success and health status measures with the TriClip device.

QUESTIONS TO THE FDA

Dr. Yuh questioned the improvement in KCCQ scores by about seven or eight points at the one-year mark for crossover patients, suggesting a potential placebo effect. Dr. Moscucci commented on the difficulty in distinguishing between placebo and real effects due to reduced TR. **Dr. Lange** requested more detailed information on mortality and heart failure admissions in the crossover group. **Dr. Krucoff** raised concerns about the KCCQ's relevance to right ventricular symptoms and suggested stratifying results based on left ventricular function. **Dr. Lange** and **Dr. Zuckerman** agreed to ask the sponsor for further analysis on left ventricular function and outcomes. **Dr. Kevit** suggested directing such questions to the sponsor. **Dr. Zuckerman** suggested examining a larger heart valve study for similar analyses. **Dr. Lange** indicated the need for the sponsor to address these questions after the FDA session.

Dr. Cizik sought clarification from Dr. Farb regarding the FDA's view on the KCCQ as a general health status questionnaire, to which Dr. Farb explained that the KCCQ is deemed acceptable for assessing health status in the specific patient population under consideration. **Dr. Shanker** commented on the high percentage of patients with NYHA class two or three symptoms and raised the question of whether the therapy would be appropriate for patients already in sinus rhythm, emphasizing the potential impact on KCCQ scores. **Dr. Friedman** inquired about medication usage breakdown in the control arm and questioned the absence of a sham arm in the study design. **Dr. Lange** requested information on baseline and 12-month medication usage for both device and control groups, with **Dr. Spinner** indicating that there was little to no change in medication usage throughout the study period.

Dr. Spinner suggested addressing the crossover data, and **Dr. Sorajja** provided information on the crossovers, stating that about half of the control population crossed over due to persistent severe symptomatic TR. He presented data on heart failure hospitalizations and mortality through two years, noting trends in favor of the device group but acknowledging the limited sample size for analysis.

OPEN PUBLIC HEARING

Dr. Asma Hussaini, a physician assistant with over 20 years of experience in transcatheter valve therapies, shared her insights on the TRILUMINATE Pivotal Study. She emphasized the profound clinical improvements seen in patients treated with the TriClip device, highlighting a specific case where a patient experienced significant relief after receiving the TriClip procedure following heart failure admissions and orthopnea symptoms. **Dr. Hussaini** described the daily struggles faced by patients with right heart failure symptoms, including difficulty sleeping, hepatic congestion, leg edema, and even requiring wound care due to swelling. She emphasized the limited treatment options available for these high-risk patients, primarily relying on diuretic therapy, which can be challenging due to poor renal function. Ms. Hussaini advocated for the approval of the TriClip procedure by the FDA, stating that it would provide interventional cardiologists with a much-needed treatment option for patients with tricuspid valve disease, complementing existing surgical interventions for other valve diseases.

Dr. Anita Asghar, a cardiologist at the Montreal Heart Institute with extensive experience in structural heart disease intervention, shared her experience with tricuspid edge-to-edge repair, specifically with the TriClip device. She recounted her involvement in the TRILUMINATE trial, which coincided with the onset of the COVID-19 pandemic in 2020. **Dr. Asghar** described the challenges faced due to the pandemic, including halted research trials and procedures, leading to a backlog of TR patients requiring treatment. Despite the obstacles,

permissions were eventually granted to resume procedures due to the significant impact of these patients on hospital resources.

Over the following three years, **Dr. Asghar** treated nearly a hundred patients with TR, witnessing improvements in their quality of life and a reduction in hospital readmissions for right-sided heart failure. She highlighted the safety and efficacy of the procedure, with patients experiencing minimal inconvenience and significant improvements in their ability to engage in daily activities. **Dr. Asghar** emphasized the importance of addressing tricuspid valve disease to improve patient outcomes and alleviate strain on healthcare resources.

Dr. Matthew Price, Director of the Cardiac Catheterization Laboratory and Interventional Cardiologist at Scripps Clinic in La Jolla, California, expressed gratitude for the opportunity to share his experience with TR treatment. Having participated in the TRILUMINATE trial, Dr. Price emphasized the profound impact of addressing TR on patients' lives. He recounted cases where patients with severe TR experienced debilitating symptoms such as fatigue, edema, and chronic ulcers, which significantly diminished their quality of life. Through the trial, **Dr. Price** witnessed remarkable improvements in patients' conditions following tricuspid edge-to-edge repair, with symptoms alleviated and daily activities restored.

Dr. Price highlighted the importance of considering patients' day-to-day experiences and functional abilities when evaluating treatment outcomes. He underscored the transformative effect of TR treatment on patients' lives noting instances where patients regained mobility, independence and joy in everyday activities.

Geneva Gail Franks, an 80-year-old participant in the TRILUMINATE study, shared her journey with severe TR and the transformative impact of the TriClip procedure on her quality of life. Initially experiencing debilitating symptoms such as arrhythmia and exhaustion, she opted for medication treatment until her symptoms worsened. Upon enrollment in the clinical trial and undergoing the TriClip procedure in February 2020, **Mrs. Franks** experienced noticeable improvements in her ability to climb stairs, manage atrial fibrillation and withstand high altitudes without arrhythmia episodes. Most significantly, the procedure alleviated her exhaustion allowing her to resume daily activities without limitations.

Dr. Eugene Chung, a heart failure specialist involved in research and transcatheter procedures, highlighted the evolution of treatment options for TR and the significance of addressing this condition. He emphasized the under-recognition of TR's impact and the need for effective interventions given its association with poor outcomes. **Dr. Chung** discussed the unique clinical presentation of TR patients focusing on progressive decline in functional status and symptoms related to right ventricular failure. Regarding the TRILUMINATE trial, he underscored the procedure's success in reducing TR severity safely offering a potentially valuable tool for managing severe TR.

Erin Lambert, wife of Brody Lambert, shared their family's journey with Brody's heart condition, beginning with his diagnosis of cardiomyopathy at 24 years old. Despite initial concerns about his prognosis, Brody's health improved with medical treatment, allowing him to lead a fulfilling life. However, nine years later, his heart function deteriorated, necessitating the implantation of a left ventricular assist device until he received a heart transplant in 2016.

After experiencing low energy and fluid retention post-transplant, Brody was diagnosed with TR, limiting his ability to engage in activities he enjoyed. Upon learning about a clinical trial for the TriClip procedure to address the regurgitation, the Lambert family decided to participate. Following the procedure, Brody experienced rapid recovery and regained his ability to work on the farm, engage in outdoor activities, and start his own construction company.

Ms. Lambert expressed gratitude for modern medicine and the advances that have prolonged Brody's life and improved their family's quality of life. She thanked the medical professionals involved in Brody's care and expressed appreciation for their dedication and sacrifices. Erin concluded by expressing gratitude for the consideration of TriClip approval, acknowledging the positive impact it has had on their family.

Dr. Pat McCarthy, Executive Director of the Bloom Cardiovascular Institute, highlighted the severity of TR, emphasizing its disabling and life-threatening nature. He explained that traditional open-heart surgery for TR is high-risk which leads to delays in treatment until symptoms are advanced. This results in poor outcomes for many patients. McCarthy advocated for transcatheter therapies like the TriClip procedure, which offer safer alternatives and can improve quality of life.

Gregory Jordan, a participant in the TriClip trial, shared his personal journey with heart disease and his decision to undergo the procedure. Despite previous health challenges, including kidney failure and transplantation, Jordan experienced significant improvements in his quality of life post-TriClip. He expressed gratitude for the opportunity to participate in the trial and emphasized the importance of sharing positive experiences to provide hope to others facing similar health struggles.

Suzanne Aguilar, another TriClip trial participant, recounted her battle with atrial fibrillation and the debilitating effects of TR. She described her decision to undergo the TriClip procedure as life-changing, leading to a quick recovery and restored normalcy to her life. Aguilar urged decision-makers to consider the impact of their choices on individuals like herself, emphasizing the need for options that restore health and vitality to those suffering from TR.

Rich Ayers, a retired Naval officer from San Diego, California, shared his experience with atrial fibrillation and subsequent tricuspid valve issues. Despite initially managing atrial fibrillation with medication, **Mr. Ayers** faced worsening symptoms, including significant weight gain due to TR. After a prolonged hospitalization, **Mr. Ayers** opted for the less risky tricuspid clip procedure over traditional surgery, leading to a notable improvement in his quality of life. He emphasized the importance of offering the tricuspid clip surgery to others with similar issues.

Dr. Lindsay Videnieks, Executive Director for Heart Valve Voice U.S., advocated for considering the perspectives of the 1.6 million people living with tricuspid heart valve disease and their caregivers. Highlighting the progressive and fatal nature of severe TR, **Dr. Videnieks** stressed the need for less invasive treatment options, given the high mortality rate among patients on medical therapy alone. She urged the advisory committee and the FDA to prioritize patient needs and consider approving new technologies for heart valve disease treatment.

Dr. Aaron Horn Jr., a structural and interventional cardiologist from northern New Jersey, represented the Association of Black Cardiologists and highlighted several key points regarding the approval of the TriClip device. Firstly, he advocated for increased diversity in clinical research, emphasizing the importance of including diverse racial and ethnic populations in clinical trials. Secondly, he stressed the need for minimally invasive treatments for severe TR. Thirdly, **Dr. Horn** emphasized the importance of addressing cardiovascular health concerns specific to the African American population and advocating for tailored solutions. He also highlighted the importance of ensuring equitable access for African Americans to cutting-edge medical devices and urged the committee to apply lessons learned from historical challenges in accessing transcatheter therapies. Finally, **Dr. Horn** pointed out the high morbidity and mortality associated with tricuspid valve disease, particularly among African Americans, and cited research suggesting racial disparities in long-term survival rates. He concluded by expressing

appreciation for the opportunity to share the Association of Black Cardiologists' perspectives and emphasized the importance of continued communication on these issues.

Dr. DeBattista, representing the Partnership to Advance Cardiovascular Health (PATCH), emphasized the importance of including the patient perspective in assessing the approval of novel cardiovascular technologies. PATCH advocates for policies and practices that promote innovation and improved cardiovascular health for patients. They stress the need for tailored treatments and innovative solutions to address the unique needs of cardiovascular disease patients. **Dr. Josie Cooper**, from the Alliance for Patient Access (AFPA), highlighted the unmet need for minimally invasive treatment options for patients with TR, urging the FDA to consider the value of new, less invasive treatments. AFPA emphasizes patient-centered care and supports policies that reinforce clinical decision-making and protect the clinician-patient relationship.

Dr. Lange concluded the open public hearing, thanking all the speakers for their important and insightful contributions to the FDA meeting.

PANEL DELIBERATIONS

During the panel deliberations, **Dr. Lange** outlined the process, stating that public observers could not participate unless specifically requested by the panel chair. **Dr. Spinner** presented data in response to questions raised by **Dr. Krucoff** regarding sites performing fewer than five procedures and the MitraClip experience for those sites. **Dr. Spinner** displayed a slide showing the distribution of TriClip enrollment per site and the average number of MitraClip cases performed before 2019, indicating that sites with varying TriClip enrollment numbers had similar experiences with MitraClip.

Dr. Lange expressed interest in the outcomes of patients with moderate or more severity TR compared to those with less severity. **Dr. Spinner** responded by showing a slide depicting the primary analysis patient population and those randomized or rolled-in. The data showed that patients with moderate TR and even those with more severe TR experienced improvement in their condition, with increased reduction in TR resulting in increased benefit in KCCQ scores.

Dr. Lange questioned **Dr. Cohen** about the claim of removing the placebo effect by analyzing only the device arm of the study. **Dr. Cohen** clarified that while the placebo effect is inherent, the focus was on examining the additional effect of the change in TR on top of the placebo effect. **Dr. Cohen** emphasized that including control patients who knew they didn't receive treatment would have introduced more significant challenges, whereas all patients in the study arm received treatment, leveling the playing field regarding the placebo effect.

Dr. Cizik expressed concerns about the placebo effect and the lack of discussion on minimally clinically important differences and anchor versus distribution-based methods in the context of patient-reported outcome measures. She questioned whether a five-point change in the KCCQ score is meaningful and sought clarification from Abbott and the FDA. **Dr. Zuckerman** from the FDA addressed the issue of training effect differences between small and large sites, emphasizing that regardless of the cutoff point used, low-volume sites consistently showed different results compared to high-volume sites. **Dr. Krucoff** inquired about the FDA's stance on the learning curve and supervision when the device is commercially available. The FDA acknowledged the gradient in results between low-enrolling and high-enrolling sites and discussed the implications for device deployment.

Dr. Vidovich raised a point regarding the apparent discrepancy between the extensive MitraClip experience at lower-enrolling sites and their outcomes with the TriClip device. **Dr.**

Spinner from Abbott responded, highlighting that while MitraClip experience was a threshold requirement, there's always a learning curve with new technology. **Dr. Shanker** expressed confusion about why such a difference in patient-reported outcome metrics would be linked to low-volume sites despite the high procedural success rate across all sites regardless of enrollment volume. **Dr. Spinner** and **Dr. Zuckerman** from the FDA acknowledged the complexity of the situation and discussed the unexplained variation in heart failure hospitalizations. **Dr. Krucoff** suggested that previous experience with the TriClip device may have contributed to safety outcomes not captured in the win ratio analysis, emphasizing the importance of understanding how experience with the device impacts overall outcomes.

Dr. Yuh expressed difficulty understanding the differences in win ratios between smaller and larger centers, particularly in light of similar technical success rates but varying outcomes in heart failure hospitalizations and changes in the KCCQ. He questioned whether these differences implied disparate patient populations or variations in optimal medical therapy between the two categories of centers. **Dr. Spinner** invited **Dr. Shu** to provide a statistical perspective on the win ratio, highlighting that baseline characteristics and predictors for heart failure hospitalizations varied between small and large centers. However, **Dr. Lange** noted that while heart failure hospitalizations predicted future hospitalizations, a treatment effect was not observed regardless of the baseline rate. **Dr. Hauptman** suggested considering the baseline KCCQ scores and the possibility of a plateau effect, where patients with higher baseline scores may experience muted benefits from the TriClip device. **Dr. Sorajja** further emphasized the importance of baseline differences in KCCQ and heart failure hospitalizations in influencing the win ratio.

Dr. Schwartzott inquired about additional data from Canada or the European Union to support the findings presented. **Dr. Spinner** deferred to **Dr. Lutz**, the Principal Investigator of the post-market study in Europe, who shared encouraging results from the European experience. **Dr. Lutz** reported similar outcomes to the pivotal study, with slightly higher rates of MAEs in a less controlled environment. He attributed this to treating sicker patients with more complex anatomies and higher baseline TR. **Dr. Lutz** also highlighted improvements in device iteration, procedural strategies, and imaging, indicating a steeper learning curve and better outcomes over time. He emphasized the importance of a training program to ensure the transfer of knowledge and skills to new practitioners.

Dr. Zuckerman raised a concern to **Dr. Sondergaard** regarding the challenges of measuring KCCQ follow-up data, citing past disappointing experiences with other registries. **Dr. Sondergaard** acknowledged the issue and mentioned using existing mechanisms like the TVT (Transcatheter Valve Therapy) registry and CMS (Centers for Medicare & Medicaid Services) linkage for up to five years. However, **Dr. Zuckerman** emphasized the need for new strategies to ensure reliable KCCQ data collection, expressing disappointment with previous efforts. **Dr. Lange** intervened, emphasizing the importance of finding effective solutions for post-market data collection. **Dr. Spinner** from Abbott assured their commitment to working with the FDA and exploring alternative approaches if necessary. **Dr. Brindis** from the NCDR (National Cardiovascular Data Registry) also emphasized their dedication to improving data collection, welcoming collaboration with Abbott to address the challenges.

Dr. Yuh from the panel directed a question to the sponsor regarding the possibility of a reduction in diuretic requirement over time among patients receiving the device, emphasizing its importance in assessing the durability of positive effects. **Dr. Spinner** responded, stating that while there was no evidence of such reduction at the time, they were interested in exploring it further as they continue to follow the patients. **Dr. Sorajja** added that there were no prescribed

changes in diuretics as part of the protocol, and any adjustments were made at the discretion of the local heart team. **Dr. Bart** raised a question about optimal medical therapy, seeking clarification on the criteria used and the medication regimen followed in the study. **Dr. Lange** welcomed this question as a segue into discussing right heart catheterization data and medication details, which **Dr. Benza** provided, highlighting the parameters considered for patient eligibility and the medication regimen maintained throughout the study. **Dr. Lange** then requested data on baseline medications and changes over the 12-month period, which **Dr. Benza** presented, indicating stability in the pillars of therapy for both device and control groups.

Dr. Hirschfeld inquired about the gradient right atrial pressure and right heart catheterization conducted post-procedure. **Dr. Spinner** then assigned **Dr. Hahn** to address this. **Dr. Hahn** explained that the mean gradient increase after the TriClip device was less than 3 millimeters of mercury, which is lower than expected for significant tricuspid stenosis. She noted challenges in measuring pressure halftime due to the high prevalence of atrial fibrillation in the patient population, rendering estimates inaccurate. **Dr. Hahn** emphasized that despite these limitations, the improved forward flow observed suggests that higher gradients in the right atrium did not impede systolic filling.

Dr. Spinner addressed two independent questions. Regarding patients with prior aortic and mitral intervention, approximately 40% of the patients had such interventions. A subgroup analysis was conducted, indicating that whether patients had prior mitral or aortic interventions or not, the results were similar. There was no significant difference in all-cause mortality, tricuspid valve surgery, or heart failure hospitalization. However, there was an improvement in the KCCQ scores, consistent with the findings from the primary analysis of the cohort.

Dr. Selzman raised the question of whether there could be a more quantitative approach to managing patients with TR using surgical, medical, or MitraClip interventions. **Dr. Adams** responded, expressing support for MitraClip technology, and suggesting that it could lead to earlier treatment for severe TR. He emphasized the importance of involving surgeons in the decision-making process and suggested that transcatheter interventions may become the primary approach for a majority of TR patients, especially those at higher risk. **Dr. Adams** also highlighted the significance of quality-of-life measures like the KCCQ in guiding treatment decisions and emphasized the commitment to furthering its adoption in clinical practice.

Dr. Krucoff raised a question about atrioventricular synchrony and the potential impact on outcomes, particularly in patients with poorer ventricular function. He suggested that differences between atrial fibrillation and sinus rhythm could be more pronounced in these patients and emphasized the importance of understanding how ventricular function affects outcomes, especially in the context of tricuspid valve interventions. **Dr. Spinner** responded by providing data on left ventricular ejection fraction (LVEF), showing that patients with LVEF $\leq$ 50% had similar outcomes regardless of whether they received TriClip or standard treatment, with both groups showing improvements in KCCQ scores.

Dr. Spinner addressed a question regarding patients with CIED-induced TR, stating that 100% of those patients experienced a reduction in TR to moderate or less, with a significant improvement in KCCQ scores. **Dr. Hahn** provided an overview of echo parameters through 12 months, highlighting improvements in TR severity and trends in RV remodeling. **Dr. Cavalcante** expanded on the imaging sub-study findings, emphasizing reverse remodeling of the right atrium, tricuspid annulus, and right ventricle, despite a decrease in right ventricular ejection fraction due to volume removal. **Dr. Benza** discussed changes in natriuretic peptide levels,

noting modest changes and emphasizing the influence of age, gender, and atrial fibrillation on NT-proBNP levels.

FDA QUESTIONS

Question One

Ms. Naber Presented question one. The discussion revolved around the safety outcomes of the TriClip device compared to the control group at 30 days and 12 months post-procedure. The Kaplan Meier estimates showed high freedom from MAEs for both the randomized and single-arm cohorts. The individual MAE components were presented, indicating favorable outcomes. The Clinical Events Committee adjudicated adverse event rates at 12 months were also discussed. **Dr. Blankenship** expressed reassurance regarding the safety profile of the TriClip device, with a note about potential future issues related to re-instrumentation. **Dr. Vidovich** echoed this sentiment, noting that considering the anticoagulation status of the patients, the observed MAE rate was acceptable. The panel generally expressed satisfaction with the safety outcomes, especially given the high-risk patient population.

Question Two

Ms. Naber Presented question two.

Dr. Blankenship highlighted the statistical significance of the results and noted a moderate to large difference in quality-of-life as indicated by the KCCQ scores. **Dr. Krucoff** emphasized the clinical significance, particularly in terms of quality-of-life improvements, despite acknowledging uncertainties regarding long-term effects on mortality and heart function.

Dr. Katz raised concerns about the overall effectiveness of the procedure, noting that while there was some improvement in TR and KCCQ scores, the other hard metrics (mortality and heart failure hospitalizations) were not significantly changed. He also expressed concerns about the procedure's long-term viability, given the availability of tricuspid valve replacement options.

Dr. Vidovich suggested additional statistical analysis to address concerns about the win ratio method. In response, **Dr. Zuckerman** defended the use of win ratio analysis stating it has gained traction in clinical trial analysis over the last decade for its ability to highlight differences in composite endpoints.

Dr. Brindis and **Dr. Hirschfeld** discussed the importance of patient-reported outcomes like the KCCQ for decision-making in the absence of significant changes in hard endpoints. They also touched on the study's limitations, including its duration and the heterogeneity of the patient population.

Dr. Cizik and **Dr. Hauptman** echoed the sentiment that the study's findings, particularly the improvements in KCCQ scores, were clinically significant and indicative of a positive impact on patients' quality of life. However, they also acknowledged the need for further research to better understand the intervention's long-term effects and identify the patient population that would benefit the most. The discussion concluded with a recognition of the TriClip device's potential benefits, while also noting areas where further investigation and post-market surveillance might provide additional insights, especially regarding the optimal management of patients with right-sided heart disorders and the generalizability of study results.

QUESTION 3

Ms. Naber Presented question three.

Dr. Lange summarized the group's consensus, indicating that despite statistical significance concerns, all measures (SF-36, KCCQ scores, New York Heart Association Class III patient numbers at 12 months, annualized hospitalization rates for right heart failure, and imaging endpoints like echo, MRI, and CT) are trending positively. This trend supports the hypothesis that reducing TR correlates with improved KCCQ scores. **Dr. Lange** invited any dissenting opinions and asked if the summary satisfactorily addressed the FDA's concerns. **Dr. Zuckerman** confirmed it did, indicating readiness to proceed to the next question.

QUESTION 4

Ms. Naber Presented question four.

Dr. Friedman expressed concerns about the safety aspect, particularly regarding the higher incidence of major bleeding in the single-arm study questioning its significance without a comparative arm. However, he still considered it within a reasonable safety range. **Dr. Zuckerman** interjected to clarify that although the study was single-arm, it had set performance goals for both safety and effectiveness, and the study met these goals.

Dr. Krucoff then shared his perspective, emphasizing reassurance from the additional randomized patients beyond the initial 350. He was particularly struck by the higher than expected percentage of patients achieving a reduction to moderate or less TR, suggesting this finding warrants further investigation into the expectations for effect size in severe patients and potential implications for post-market label extensions or device design modifications. He highlighted the importance of addressing TR adequately, given the long-term consequences of leaving TR unaddressed, contrasting the slow, debilitating progression of right heart failure with the acute distress often seen in left heart failure.

Dr. Friedman raised concerns about safety due to higher rates of major bleeding and questioned the significance of the findings without a comparison group. **Dr. Zuckerman** clarified that the study, despite being single-arm, measured against performance goals for safety and effectiveness. **Dr. Yuh** and **Dr. Shanker** echoed the sentiment that the device performed better than expected. **Dr. Shanker** highlighted effective treatment in patients with device-induced TR.

Dr. Krucoff discussed the implications for defining the device's intended use population, noting the success in a high-risk group and pondered the expansion of the patient population for the device. **Dr. Bart** provided a more cautious view, acknowledging the technical success but pointed out the worse clinical outcomes in the study's cohort compared to the randomized group, and emphasized the need for careful patient selection.

Dr. Lange's summary acknowledges the achievement of the study's endpoint -- the significant reduction in TR in 80% of patients who were not expected to respond as well -- and suggests that the device could be beneficial even for patients with severe TR who are not surgical candidates. The discussion concludes with readiness to move on to the next question, indicating a thorough examination of the device's performance and potential patient impact.

Dr. Lange acknowledged the study's achievement of its endpoint highlighting the significant reduction in TR in 80% of patients who were not initially expected to respond favorably. He suggested that the device could be beneficial even for patients with severe TR who are not candidates for surgery.

QUESTION 5

Ms. Naber Presented question five.

Dr. Lange initiated a discussion with a request for opinions on proposed indications for a medical device, starting with a call for a show of hands. **Dr. Brindis** supported the clinical data backing the proposed indications and suggested changing the term "heart team" to "multidisciplinary team" for inclusivity. **Dr. Vidovich** concurred on the data's support for the indication but suggested refining the language used for health status improvement. **Dr. Shanker** emphasized including NYHA class specifications to prevent misuse in severely sick patients and noted the prevalence of atrial fibrillation among the study participants. **Dr. Blankenship** expressed discomfort with the vague language on health status improvement, proposing a focus on patient's perception. **Dr. Cizik** found the terms too generic, advocating for specificity, especially in reflecting significant improvements in quality of life for those with lower baseline levels.

Dr. Friedman echoed the need for clarity and specificity, suggesting the inclusion of functional quality of life improvements as determined by a multidisciplinary team. **Dr. Hauptman** raised concerns about the severity grading of TR, suggesting limitations to more severe cases. **Dr. Hirshfeld** warned against micromanaging indications, advocating for a broader approach to remain adaptable to clinician judgment and patient variability.

Dr. Lange summarized the discussion, emphasizing specificity in describing health status improvements, the role of a multidisciplinary team, the focus on severe and symptomatic TR, the exclusion of class four patients from assessments, and the consideration of prevalent atrial fibrillation in patients. This summary encapsulated a comprehensive view toward refining and improving the device's proposed indications based on expert opinions.

QUESTION 6

Ms. Naber Presented question six.

Dr. Lange discussed the safety and effectiveness of the medical device, focusing on its benefit-risk profile in preparation for a voting session. **Dr. Yuh** expressed comfort with the device's safety and placed significant trust in the KCCQ data, despite acknowledging a potential placebo effect. He emphasized the importance of patient experience and supported the FDA's patient-centric initiatives.

Dr. Bart concurred noting the adequacy of the safety profile and the limited alternatives for patients thus favoring the device's overall benefit. **Dr. Blankenship** highlighted the favorable safety profile compared to other procedures and suggested that symptom relief alone justified the device's use, given its low risk.

Ms. Schwartzott advocated for the device from a patient perspective emphasizing the importance of having low-risk, minimally invasive options available, especially for heart failure patients. **Dr. Katz** pointed out the absence of evidence regarding the device's impact on paracentesis needs or peripheral edema reduction but suggested its potential usefulness in patients with severe right ventricular failure who cannot undergo valve replacement.

Dr. Krucoff supported the device's approval with reservations about its application in younger patients and its potential to limit future surgical options. **Dr. Hauptman** echoed these concerns, urging the FDA to ensure post-implant safety, particularly regarding future needs for defibrillator or pacemaker leads.

The discussion concluded with a consensus on the device's low perceived risk and its symptomatic benefits, alongside caution regarding its long-term implications and the need for further post-approval studies. **Dr. Lange** summarized the sentiments, acknowledging the thought-provoking nature of the discussion and the anticipation of detailed explanations for

individual votes on the device's approval. The session then moved to considerations for a proposed post-approval study.

QUESTION 7

Ms. Naber Presented question seven.

Dr. Krucoff highlighted the importance of post-market surveillance for the breakthrough device, focusing on the quality-of-life impact demonstrated by KCCQ scores and understanding the role of rhythm and left ventricular function in patients with tricuspid regurgitation.

Dr. Brindis provided background on tricuspid procedures and underrepresented minorities in the TVT registry, emphasizing the strengths of using a large patient cohort and CMS claims data for comprehensive follow-up, while noting the importance of improving KCCQ data collection.

Dr. Cizik called for the inclusion of two and five-year KCCQ data and suggested collecting more specific symptom data to better understand patient experiences post-procedure.

Dr. Yuh saw the study's duration as an opportunity to assess the intervention's impact on managing tricuspid disease and right heart failure, especially among minority and underrepresented groups with less access to medical follow-up.

Dr. Vidovich questioned the granularity of data regarding rhythm issues and the impact of implantable devices on TR.

Ms. Schwartzott supported the use of registries for data collection and emphasized the importance of studying subgroups, particularly younger populations who will live with the device longer.

QUESTION 8

Ms. Naber Presented question eight.

Dr. Lange and **Dr. Blankenship** discussed the necessary training for interventionalists regarding a new procedure, emphasizing the importance of experience, especially with prior MitraClip procedures, and the involvement of the entire care team before, during, and after the procedure. **Dr. Krucoff** highlighted the differences between mitral and tricuspid valves but believed that the training model used for MitraClip could be applied. He also stressed the importance of post-procedure care by someone knowledgeable in right heart failure.

Dr. Vidovich raised concerns about the translation of MitraClip experience to better outcomes suggesting the heart failure team's role as crucial. **Dr. Brindis** focused on patient selection as a major component of training programs, while **Dr. Shanker** shared insights on the technical challenges of maneuvering around the tricuspid valve compared to the mitral valve due to anatomical differences indicating a need for specific skills and experience.

Dr. Friedman pointed out the critical role of advanced imaging and the importance of a competent echocardiographic team for proper patient assessment. **Dr. Lange** summarized the discussion by highlighting four key components for success: extensive MitraClip experience, careful patient selection, skilled imaging teams, and effective heart failure management, possibly by a multidisciplinary team.

VOTE

Dr. Awojope outlined the FDA's process for reviewing medical device pre-market applications (PMAs) according to the medical device amendment to the Federal Food, Drug, and Cosmetic Act, further amended by the Safe Medical Devices Act of 1990. He emphasized that

the panel's recommendation must be based on the safety and effectiveness data presented in the application or available public information. **Dr. Awojope** defined safety, according to 21 CFR section 860.7(d)(1), as a device being considered safe if its benefits outweigh any probable risks when used as intended with adequate directions and warnings. Effectiveness, defined in 21 CFR Section 860.7(e)(1), is established when a device is likely to produce clinically significant results in a significant portion of the target population under its intended use conditions.

The panel was then instructed to begin the voting process on the PMA, with **Dr. Awojope** announcing he would read the three voting questions and send an email to each voting member to collect their responses. Voting members were reminded to vote on each question and include their names on their ballots. After reading all three questions, the votes would be tallied and officially recorded.

VOTING QUESTIONS

The voting process led by **Dr. Awojope** involved three key questions regarding the Abbott TriClip G4 System's safety, effectiveness, and the balance of benefits versus risks for patients fitting the proposed indications. Each question required panel members to vote "yes," "no," or "abstain."

Question one: The panel was asked if there is reasonable assurance that the Abbott TriClip G4 System is safe for its intended patient group. There was a pause to ensure all members had access to necessary materials, and a reminder was given to vote.
Questions two: The next query focused on the system's effectiveness for the specified patient criteria. After confirming all members could participate, the panel was instructed to vote.
Question three: The final question asked if the benefits of using the Abbott TriClip G4 System outweighed its risks for the intended patients. Following this, a break was announced to tally the votes, with results to be shared after.

The process underscored the importance of ensuring all panel members had the opportunity to review relevant information and vote on each critical aspect of the system's approval consideration.

VOTE RESULTS

Dr. Lange reconvened the session to announce the voting results for the Abbott TriClip G4 System, which **Dr. Awojope** then detailed:

Question one: The panel unanimously agreed (14 yes, 0 no, 0 abstain) that there is reasonable assurance the system is safe for patients who meet the specified criteria.
Question two: The vote showed strong support (12 yes, 2 no, 0 abstain) for the system's effectiveness in the specified patient group.
Question three: The panel largely affirmed (13 yes, 1 no, 0 abstain) that the benefits of the system outweigh its risks for the intended patients.

SUMMARY OF PANEL RECCOMENDATIONS

Dr. Lange thanked **Dr. Awojope** for presenting the voting results and then invited panel members to discuss their votes, emphasizing the importance of stating their names, how they

voted for each question, and if changes to labeling, restrictions on use, or controls could alter their negative votes.

Dr. Blankenship voted "yes" on all questions, comparing TriClip's safety with other devices and highlighting its statistical significance in improving patient outcomes.

Dr. Brindis also voted "yes" across the board, foreseeing the device as an essential tool for managing tricuspid regurgitation.

Dr. Bart voted “yes” on all questions and echoed the sentiment, finding the safety data compelling and the patient-related outcomes important.

Dr. Cizik expressed concerns about the correct patient population but ultimately voted "yes" on all questions, appreciating the compelling data presented.

Dr. Evans emphasized the need for analyzing outcomes in relation to patient experiences, voting "yes" for all questions but noting concerns with the win ratio analysis.

Dr. Friedman recognized the device's potential despite unanswered questions about its future impact, voting "yes" on all.

Dr. Hauptman had reservations about effectiveness and voted "no" on question two and three but acknowledged the device's safety in his other "yes" vote.

Dr. Hirshfeld supported the device's availability for interventionists despite desiring more rigorous efficacy data.

Dr. Katz expressed a nuanced view, voting “yes” on safety and ultimately voting "yes" for the benefit-risk balance despite voting "no" on effectiveness.

Dr. Krucoff highlighted the breakthrough nature of the device and its potential for learning in post-market evaluations, voting "yes" for all.

Dr. Krucoff , **Dr. Shanker**, and **Dr. Vidovich** shared optimistic views on the device's role in treating right heart failure and its safety, voting "yes" on all counts.

Dr. Yuh emphasized the meaningful advance the device represents in treating right heart failure, voting “yes” on all.

Dr. Lange concluded the session by thanking everyone involved, especially highlighting the study's conduct and the collaborative efforts between the sponsor and the FDA. **Dr. Zuckerman** expressed gratitude to **Dr. Lange** and the panel for their diligent work on a challenging file.

ADJOURNMENT

Dr. Lange expressed gratitude at the conclusion of a successful meeting in El Paso, humorously referring to the celebration as "ita" time, a combination of fajitas and margaritas. He then officially adjourned the meeting of the Circulatory System Devices Panel, thanking all participants for their dedication and service throughout the day.

I approve the minutes of this meeting as
recorded in this summary.

I approve the minutes of this meeting as recorded in this summary.

Richard A. Lange, M.D., MBA
Temporary Chairperson

I certify that I attended this meeting on February 13, 2024 and that these minutes accurately reflect what transpired.

Akinola A. Awojope -S

Digitally signed by Akinola A. Awojope -S
Date: 2024.06.03 16:37:10 -04'00'

Akinola A. Awojope, MPH, DrPH.
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August 10, 2022