# TCT 2013

Live Case Transmissions: Overview & Technical Specifications

> San Francisco, California March, 2013

#### **TCT 2013 Transmission Overview**

#### Introduction

Thank you again for agreeing to have your medical center participate as a LIVE CASE TRANSMISION SITE at the 25th Annual Scientific Symposium of Transcatheter Cardiovascular Therapeutics (TCT) 2013 managed and developed by the Cardiovascular Research Foundation (CRF). This year's meeting will be held Monday, October 28<sup>th</sup> through Friday, November 1st, 2013.

From the beginning, the clinical case transmissions have always been the heart and soul of TCT. We are committed to making the live case presentations at TCT 2013 rich in relevant content, innovative from the standpoint of new interventional techniques, and educationally satisfying to a widely diverse audience of healthcare professionals.

The case transmission schedule for TCT 2013 involves 20 international centers and 46 hours of live cases in three separate venues - Main Arena, Coronary Theater, and Endovascular and Structural Heart Theater. All live cases will be transmitted Tuesday through Friday, October 29<sup>th</sup> to November 1st, 2013.

In this handout we provide extensive details regarding operational logistics and specific educational objectives, as well as initiating the process of communication with our media experts. TCT audiovisual consultants will coordinate communication and help to define the specific requirements to facilitate the case transmissions from your site.

A supplemental document, focusing specifically on the technical specifications needed to transmit live cases into TCT 2013, has been created and will be distributed to your designate video producer. This "Technical Cut Sheet", will cover the technical details, procedures and issues related to the production and transmission of live cases. It could also serve as a reference for future productions, beyond TCT 2013.

Our goal is to have all sites transmit in the High Definition (HDTV) video format. With twenty locations from around the world transmitting live cases into a single event, TCT 2013 will be one of the largest High Definition Television (HDTV) events in the world. TCT is proud of setting such a comprehensive standard for the use of this technology. The goal of TCT has always been to provide its attendees the best in content delivery, most up to date subject matter, and the most insightful and relevant live case material. The utilization of the HDTV video technology is helping us meet this goal.

#### The Production Components

#### Individual Roles and Responsibilities

There are many individuals working for the successful production and transmission of live cases, and TCT 2013 is a team effort. There are several components to this effort: Medical Content, technical production, administration and logistics.

#### At each transmission site, the following roles must be designated:

**Primary Doctor or Site Director** – The lead physician at the transmission site presenting live cases. The Primary Doctor is the main point of contact for medical issues, case selection, and issues of content during the live case transmission. He or she will designate a staff member to be the Live Case Coordinator.

In addition, we strongly recommend the lead physician assign an additional physician to help with communication and creation of the patient history slides.

**Live Case Coordinator** – Coordinates all logistical and administrative responsibilities at the transmission site. The Live Case Coordinator is the primary point of contact for the site's video producer and oversees the review and completion of all TCT 2013 related documents. The coordinator provides coordination among all in-house departments - such as legal, security and marketing - needed for the production of live cases.

**Video Producer** – Responsible for the technical production of live cases. Works primarily with the Live Case Coordinator throughout the live case production process.

• **NOTE:** If a site has no experience transmitting broadcast quality (HDTV) live cases, a TCT representative will assist in locating a qualified producer.

<u>At the Cardiovascular Research Foundation</u>, key individuals and their responsibilities are as follows:

Dr. Martin Leon and Dr. Gregg Stone – Directors of the TCT 2013 meeting.

**Dr. Giora Weisz** – Primary contact for case content, patient history slides, and a list of planned device.

**Director of Media Services** – Robert Langford, of Med-Scene, L.L.C., is responsible for all technical issues related to the live case transmissions into TCT 2013. These include:

- Providing technical specifications for video producers.
- Assist in providing a quality video production vendor, where necessary.
- Coordination of satellite and transmission services.
- Assist in the completion of the TCT 2013 Transmission Site Agreements.
- Coordination of the transmission sites' Opening Videos.

**TCT 2013 Faculty Liaison** – Denise Tong, will coordinate the procedural information for live case sites and will be responsible for any non-technical issues or questions relating directly to the live case transmissions and faculty. These include issues such as:

- Updating and distributing the Live Case Schedule
- Assisting administratively with transmission site additions and changes.
- Faculty disclosures and resolution
- Coordination of Pre-production meetings and conference calls.

**TCT Site Coordinator** – Lizette Rivera, will coordinate the contract and collect the Authorization to Use or Disclose Protected Health Information documentation from each of the live case sites.

#### Agreements, Questionnaires and Consents

The following three documents must be completed by every site transmitting live cases into TCT 2013.

- The Transmission Site Production Agreement It is necessary for every transmission site to complete an agreement in order to receive reimbursement from the Cardiovascular Research Foundation. The agreement addresses legal issues pertaining to the transmission of live cases into TCT 2013. It is a requirement that the agreement be signed by the transmission site. It details the costs of the live case production services for which the site seeks reimbursement. Detailed instructions on how to complete the Transmission Site Production Agreement are found at the end of this document.
- 2 **Transmission Site Questionnaire -** The information provided in this questionnaire will help in the final planning of the Live Case Transmission Schedule. It should be completed and returned to Cardiovascular Research Foundation as soon as possible.
- 3. The Authorization to Use or Disclose Protected Health Information: The Authorization must be completed by every patient whose case is to be transmitted into TCT 2013. At the completion of the transmission, the completed authorization should be copied, with the duplicate kept for the transmission site's records, and the original sent to Cardiovascular Research Foundation.

There are two versions of this release:

- One for sites domestic to the United States
- One for sites located outside the United States

**Important Note:** Completed copies of the "Transmission Site Production Agreement" and the "Authorization to Use or Disclose Protected Health Information" must be submitted Lizette Riveria at the Cardiovascular Research Foundation **before reimbursement for production services will be made.** 

#### **Production Details and Specifications**

#### Logistical Requirements at the Transmission Sites

Many TCT 2013 transmission sites have a history of presenting live cases. In these situations, a Standard Operating Procedure (SOP) may already be established in which lab designations and space allotments for Video Control are already established.

For sites new to the transmission of "Broadcast Quality" (HDTV) live cases, the following is a guideline of the space needed for the different production and transmission components. Also included are telephone and IT, power, security, and parking considerations

#### Lab and Space Allocation

- **Two Primary Labs** two labs are to be wired, equipped, and staffed for the video production of live cases. They are considered to be "online." Unless problems arise, they will be the only labs used during the transmission.
- Video Control this is a 100 square foot (8 square meters) space needed for the primary video production equipment required for the transmission. This area should have ample power and at least four dedicated analog or "POTS" telephone lines nearby.

#### Telephones and Information Technology (IT) Requirements

- Four analog or POTS telephone lines are needed at the Video Control location.
  - For those using "Voice Over IP" ("VOIP) or ISDN based telephone systems, please make sure your system can connect to an international POTS telephone number.
- An Internet Connection for transferring Patient History Slides or other media content.
- Access to a "Telephone Closet" should be taken into account when determining a location for Video Control.
  - This is for access to Fiber Optics provided by the local Telephone Company

#### Power

- Ample power is needed for Video Control
  - Usually six (6) 110 volt / 15 amp circuits for productions in North America.
  - All circuits must have "clean" power on the same ground.

#### Other Requirements

- The site's security department should be contacted for the following:
  - Protection of television production equipment while on site
  - Possible parking of satellite trucks on the day of transmission
  - Access of television production personnel to labs during off-hours
- The site's health and safety department should be contacted to provide guidelines for production crews and equipment.

#### **Restricted Vendor Access Requirements**

It is the site's responsibility to coordinate and provide access to the video production vendor throughout the production process. This includes the following:

• Any and all access requirements specific to the transmission sites

- Any and all costs associated to providing said access
  Any coordination or costs of maintaining restricted vendor access after the TCT 2013 production

#### Technical Specifications

#### Production and Transmission Standards

We would like all sites to produce and transmit live cases in the following video standard:

- The High Definition Television standard for TCT 2013 is <u>1920 by 1080 @59.94i</u> (interlaced)
- The signal format will be: HD-SDI ("High Definition via Serial Digital Interface.")
- Up to four (4) channels of audio need to be embedded on the video signal.

HDTV is the national video standard for the United States, yet transmitting live material in HDTV is still a relatively complex undertaking. Because there are several video formats that are considered "High Definition" by various producers around the world, it is of the <u>utmost</u> <u>importance</u> that every site conforms to the <u>1920 by 1080 @59.94i via HD-SDI</u> standard. This, for the following reasons:

- 1. It allows for the standardization of video encoders and decoders throughout the production chain
- By quoting "<u>1920 by 1080 @59.94i via HD-SDI</u>" in every conversation, later confusion is avoided
- 3. Most "good" to "high quality" video switchers will allow a video producer in any part of the world the option to output at the <u>1920 by 1080 @59.94i via HD-SDI</u> standard.
- 4. Finally and most importantly, troubleshooting throughout the transmission path is simplified by every technician using and monitoring the same video resolution and format.

#### Transmission Coordination and Standards

- TCT 2013 will coordinate, provide, and pay for the services needed to transmit the live case signal to the Convention Center.
- TCT 2013 will provide as necessary whatever equipment and personnel are necessary to transmit in the <u>1920 by 1080 @59.94i via HD-SDI</u> video format.
- However, TCT 2013 will not pay for major technical infrastructure improvements to a facility necessary to meet broadcast quality, HDTV standards
- If the transmission logistics at a transmission site is in question, a site visit by a TCT representative will be required

#### Transmission Site Production Specifications

All budgets relating to TCT 2013 video production services need to address the following video and audio sources. TCT 2013 will reimburse transmission sites for the sources specified below.

**Video Sources** – TCT 2013 will reimburse the transmission sites for the production of the following video or computer sources. Any costs related to additional sources or equipment are the responsibility of the transmission site.

- Up to two (2) cameras per lab
- Live fluoroscopy
- Angiographic/fluoroscopic road map or reference
- Hemodynamics (a.k.a. "Vitals")
- A shared channel for intravascular ultrasound (IVUS), optical coherence tomography (OCT), fractional flow reserve (FFR), near infrared spectroscopy (NIRS), intracardiac echocardiography (ICE), or transthoracic or transesophageal echocardiography (TTE or TEE)
- One spare video or computer-based image source such as CT or MRI

• Patient History Slides Computer

**Audio Sources** – It is essential that good, clean audio is provided from each site. While it may seem counter-intuitive in 2013, it is often harder to get good audio than good video. To help alleviate the problem with audio delay and "echo", a mix-minus audio configuration must be maintained at all times.

- Up to three (3) doctors on microphone per lab.
  - Clean microphone placement in terms of sterile field and technical placement is vitally important!
  - Microphones should NOT be under sterile gowns.
- Two "Return audio" channels from the TCT venue for moderators and panelists via telephone interfaces.
- Music and audio "test tone" should be available for testing and calibration.

<u>A SPECIAL NOTICE CONCERNING IN-LAB AUDIO!</u> After many years of requesting that no audio speakers be used in the labs at a transmission site during a transmission, we are now making this mandatory! Therefore, the following rules apply for audio specifications:

- NO audio speakers are to be used in a lab that is transmitting live to TCT!
  - This often creates an echo effect that is heard by the attendees at the meeting and is so distracting as to ruin the educational content of the procedure.
- All microphone signals are to be equalized and tested in advance to make sure they provide a good clean signal.
- If any transmission site production requires assistance in adhering to these two VERY IMPORTANT specifications, CRF will provide audio specialists to assist in their production.

Good, clean and intelligible audio is vital to a successful live case transmission. Although a much simpler technology to utilize, audio production is the most prone to failure. PLEASE help us to help you to produce the best series of live cases ever!

#### New Requirements – as of TCT 2013

As of TCT 2013, there will be some addition video and transmission production requirements. These focus on site specific considerations for live case productions, a means of evaluating production status while live, and an additional means of quality checking a production signal. NOTE: All of these requirements are based on real world situations during actual live case events.

- 1. For sites wishing to use wireless microphones and "in-ear monitors"please use a "Spectrum Analyzer" to determine the amount of frequency interference currently present in the procedure room. Medical imaging equipment, hospital paging systems and radio cardio monitors used in hospitals and during live case procedures generate a lot of "RF Noise". Some of this noise hits on the same frequencies needed for wireless microphones and ear monitors. An analyzer will help determine the best frequency to use during the transmission.
- Also for wireless microphones and ear monitors please provide Robert Langford the equipment make, model and frequency blocks of the wireless equipment and an evaluation will be made as to what regional radio interference – via television and radio stations – may impact their use.
- 3. All sites are required to utilize a "Return Monitor" from their satellite uplink of fiber connection to help resolve any transmission issues. The return feed

should include video and embedded audio. This greatly helps in diagnosing issues within the transmission chain.

4. It is suggested that an internet connection be available at the video control location of each transmission site. A new "video back-haul" system is being implemented that will stream a site's video and audio onto the internet. This will assist in resolving any transmission related issues that may arise during the "Connect and Test" phase of a transmission. This signal will be switched for diagnostic purposes only and should NOT be used as a return video feed.

#### Equipment and Service: What Costs Are Covered

In order to remain within budget for this event, CRF will pay each site for the following equipment and services:

- A professional HDTV video production system capable of outputting <u>1920 by 1080</u> <u>@59.94i via HD-SDI</u> and that cleanly switches between all necessary medical and production video sources
- Up to two professional video cameras per lab
- Production equipment needed to down-scan or scan-convert the necessary medical images to the **<u>1920 by 1080 @59.94i via HD-SDI</u>** video format.
- The processing of additional medical sources such as histology slides

The following costs for equipment and services will not be covered:

- Character generators
- Video recording at the site
- Use of a facility's in-house cabling or fiber "backbone"
- The production of a site's opening video
- Improvement to a site's infrastructure
- Cost of providing or maintaining restricted vendor access
  - This includes tests, immunizations, or administrative fees

Cardiovascular Research Foundation will not pay for any costs not specified in writing on the finalized **"Transmission Site Agreement."** 

Finally, <u>CRF retains the right to approve or replace the video vendor at any transmission</u> <u>site.</u> CRF will recommend video vendors if the transmission site cannot identify a company.

#### A Standard HDTV Video Production System

For sites in North America, *Med-Scene, L.L.C.* – working with several vendors – has created a "Standard HDTV Video Production System" for TCT 2013. This system, that includes all equipment and technical crew needed to produce live cases in the HDTV format of <u>1920 by 1080</u> @59.94i via HD-SDI, can be delivered to any of the North American transmission sites and adheres to the budget guidelines specified by the CRF.

This system features the following:

- Two HDTV video cameras with three 1920 by 1080p, 1/2+" CCD or CMOS outputting on HD-SDI
- Camera controls
- Five Barco/Folsom ImagePro HD scan converters for switching between multiple in-lab sources
- All video terminal and engineering equipment
- All necessary video and audio encoders and embedders

- A fully qualified Chief Engineer or Engineer in Charge who travels with the system
- The latest portable HD-SDI video switcher from Panasonic, Grass Valley, Sony or FOR-A.

For more details on utilizing this system for your site, clarification and/or additional details related to technical aspects of the transmissions, please contact the following:

Robert Langford - President Med-Scene, L.L.C. 3102 Borge Street Oakton, VA 22124 USA Office: +1(703) 934-7015 Fax: +1(703) 934-7016 E-mail: <u>medscene@cox.net</u>

#### Production Responsibilities: The Cardiovascular Research Foundation

#### **Video Production Vendors**

The Cardiovascular Research Foundation will coordinate, direct, and cover the financial costs of each site's production incurred relating to the live case transmissions into TCT 2013. It will work with each site to specify video production standards. It will also work with, or help select, a video production vendor for each site in order to ensure high quality transmission for this event.

#### **Transmission Services**

The Cardiovascular Research Foundation will coordinate and pay for all services required for transmitting the live cases from each site into TCT 2013. A site survey will be conducted - where necessary - to determine the best transmission path from each site. If necessary, additional cabling may be installed at a site in order to complete the transmission path. This task will be coordinated by companies working with the Cardiovascular Research Foundation in cooperation with representatives of the transmission site in question.

#### **Communications and Points of Contact**

The Cardiovascular Research Foundation will establish a communication "point of contact" list that will be available throughout the production of TCT 2013. (*Please see the list at the end of this document*.)

#### **Contract Templates and Legal Documents**

The Cardiovascular Research Foundation will provide all necessary contracts and legal documents related to the production of live cases into TCT 2013. This includes, for example, the Transmission Site Agreement and documents defining the rights of use of all material created during TCT 2013.

#### **Patient History Slide Template**

Patient history slides are computer generated slides created on a Microsoft® PowerPoint® template. You will receive the templates from CRF. The purpose of the patient history slides is to provide a concise overview of the patient's condition, prior medical history and procedures, and suggested plan of treatment. These slides must be completed by each transmission site and returned to the Cardiovascular Research Foundation in order to be displayed as the live case begins. They will be shown at the convention center and not transmitted from the site.

#### **Responsibilities: The Transmission Sites**

#### **Points of Contact**

The transmission site will identify to the Cardiovascular Research Foundation the following points of contact:

- **Primary Operator or Site Director** A lead physician who will be coordinating medical issues such as case selection and other operational details for the live cases at the site.
- Live Case Coordinator A member of the administrative staff who will assist in all logistical coordination of the site's transmission.
- Video Producer An individual responsible for the technical production of live cases who works primarily with the Live Case Coordinator throughout the live case production process.

#### Patient Consents, Documentation, and Other Authorizations

Each transmission site is responsible for obtaining all necessary patient consents and for the completion of other patient-related documents needed for the transmission of live cases into TCT 2013.

We would like to emphasize the importance of the live case transmissions conforming to the highest clinical, ethical, and educational standards. We must be certain that at no time is patient safety compromised for the sake of the live case transmissions and that **optimal patient safety** *is maintained under all circumstances.* 

We must be certain that all sites understand and adhere to thematic case selection criteria and reduce case content redundancy. We will encourage innovative case presentations to stimulate provocative discussion.

Importantly, we will insist upon the highest ethical standards of conduct, that requires that all case operators declare their personal conflicts of interest and fulfill other institutional case presentation requirements (such as special consent forms, appropriate FDA approvals for US operators, HIPPA documents, and video telecast consents from patients).

*It is of the utmost importance that all patients complete and sign all forms and documents to ensure full compliance with HIPAA regulations.* At the conclusion of a site's transmission, these documents should be forwarded to Lizette Rivera at the Cardiovascular Research Foundation.

In addition to this, all sites must ensure that they receive all necessary authorizations granted by all parties of interest from within the hospital, or facility in question, to transmit live cases into TCT 2013.

#### **Completion of Patient History Slides and Device Lists**

Patient history slide templates <u>will be provided to each site</u> and must be completed and returned to the Cardiovascular Research Foundation no later than October 21, 2013. The purpose of the clinical history slides is to provide a concise overview of the patient's condition, prior medical history and procedures, and suggested plan of treatment.

The clinical history slides must include all the relevant clinical history in a focused, easy to read presentation. You will receive a CRF template for this presentation. This template is to be used by all sites. Please use it only for a (short) focused presentation of the case and **not** for "mini-lectures" during the live transmission.

Patient history slides must be sent to Dr. Giora Weisz (<u>tctlivecases@crf.org</u>) no later than October 21th for review. After this date, please continue to update Dr. Giora Weisz in case of any last minute changes.

- The slide templates are individualized for the type of case coronary, endovascular, or structural. These slides will be displayed to the audience on a side screen during the case presentation introductions.
- Include and highlight in the live case worksheet devices to be used during transmission so that proper graphics materials can be obtained to enhance case presentations.

You are asked to provide a detailed strategy plan for each case. This includes list of devices (including imaging) that may be used as well as planned enrollment in a research protocol as appropriate. This information is crucial to allow us to prepare for the live cases. As in previous years, an additional simultaneous side screen will be used to project any supplemental educational slides that are relevant to the case. Knowing the planned strategy and list of devices will help us to be ready with the appropriate "factoids" and "devicoids" (device-specific graphics).

#### Specific instructions on how to complete the patient history slides:

#### 1. First slide

All items have to be focused and clear and in established medical terminology. Please avoid abbreviations that are not commonly accepted and not used internationally. This is a problemoriented presentation, focused on the patient and the procedure. Please be thoughtful, concise, and avoid irrelevant details and redundancy.

*Name of medical center* – please overwrite it with your center name. Example: Columbia University Medical Center

*City, State (or Country)* – please overwrite these. Example: New York, NY or Bonn, Germany

*Operators* - insert the names of the two senior operators of this case

Date - insert the date of the planed transmission. Example: 10-29-2013

Patient demographics - insert age and gender.

*Risk factors* - please leave in the slides only the risk factors that apply to the patient. Please delete the others. Focusing on those that exist will make it easier to read.

*Past medical history* – include only important facts that relate to the case. History of Transmission appendectomy is not relevant. Delete the lines that are not relevant: e.g. if the patient had no PCI or CABG in the past, these lines can be deleted.

*Clinical presentation* – keep only those related to the current case and with the shortest possible description.

#### 2. Second slide

Angiographic findings – very short description of the anatomy and findings. Please use abbreviations such as LM, LAD, LCX, RCA.

Procedural strategy – this is intended to specify your plan and specify the technology you intend to present. Don't list all the steps of the procedure, but only the essential details. Some examples:

Rotablator of calcified ostial RCA; SVG with BMS and embolic protection; LAD bifurcation crush technique with IVUS guidance. Please avoid names of manufacturers.

Clinical indications for doing the case. Some examples: ACS with severe stenosis of culprit lesion; CTO with angina and ischemia (nuclear imaging); severe carotid stenosis + symptoms. Regarding "endovascular" or "structural" cases – here the variety of anatomic locations and procedures is much larger than with coronary cases. The templates have a general design. Please keep the overall pattern intact, but you may change the language and definitions for better description of the case.

#### 3. Third slide

This is a blank slide that is reserved to present images of additional procedures that the patient underwent prior to the current procedure. Please restrict to the minimal number of images and attach only those that are important for understanding of the procedure. The pictures should be in the highest possible resolution.

There is no need to present the angiogram of the lesion that will be treated.

You may show pictures from prior procedures and the status of other vessels that will not have a repeat angiogram or prior intervention.

In selected coronary cases and often with endovascular and structural heart cases, it is appropriate to show images of CT scan, MRI/MRA, or other imaging studies.

This slide is not intended for literature review or presentation of devices and technologies. If you want to show a novel technology or device or an outline of a research protocol, please discuss with us in advance. As in prior years, we will have a special presentation side screen for "factoids" that is designed for such information in parallel with the live case transmission. These factoids substantially enhance the audience educational experience during your cases.

• All communications regarding the slides and list of devices should be done with Dr. Giora Weisz at <u>tctlivecases@crf.org</u>.

#### **Opening Videos**

Opening videos are required for each transmission site. The length of the video should be between 30 seconds and one (1) minute. The videos will be played at the Convention Center itself. It is, therefore, necessary for the Cardiovascular Research Foundation's Director of Media Services – Robert Langford - to receive the opening no later than October 18th to be screened and reviewed in advance.

Since the opening videos are generic and can be used for a variety of different meetings, the Cardiovascular Research Foundation will not cover the production costs of opening videos.

- Videos must be non-commercial.
- The videos' purpose is to introduce the transmission sites' location (city and country), facility, and staff to the audience at TCT.
- The videos should be delivered as QuickTime ProRes 422 files. This can be done over the internet, or via CD, Thumb-drive or SD Card.
  - Please no AVI, WMV, H.264 or MPEG-4 files.
  - All media will be returned once the Opening Video files are downloaded.

IMPORTANT: Please ensure there are no HDCP restrictions encoded into the opening video's file! This prevents distribution at the TCT 2013 meeting site.

#### **TCT 2013 General Production Details**

#### Live Cases Content and Structure

This year, again, there are three separate live case transmission venues; The Main Arena, The Coronary Theatre, and The Endovascular / Structural Heart Theatre. The content of all live cases will be determined by Dr. Martin Leon and Dr. Giora Weisz, in consultation with the primary doctor at the transmission site. This includes case type and into what venue the case will be shown.

As a general principle, live cases shown in the Main Arena feature the latest and most updated technologies in the field of Interventional Cardiovascular Therapies. All Coronary, Endovascular and Structural Heart Theatre cases are "thematic" and, as such, cases in these venues should be directed to pre-specified areas of interest. For TCT 2013, all live case sessions will be either 45 or 60 minutes in length. The Main Arena sessions are 45 minutes, and the coronary and endo/structural case sessions are 60 minutes each.

Details of each of the live case transmission venues – The Main Arena, The Coronary Theatre and the Endovascular/Structural Theatre – are as follows:

<u>The Main Arena</u> - *Emphasizes novel new devices (often non-FDA approved) or innovative treatment strategies.* Cases will focus on the latest and most topical subjects, procedures, and devices. If new devices are used during a case, please be certain that you have forwarded us the necessary graphics materials that show the essential elements of the device.

<u>The How-To-Treat Coronary Theater</u> - *This is a venue exclusive for coronary cases emphasizing operator technique and thoughtful decision-making.* Select complex cases and employ devices and techniques that are available to all practicing interventionalists. Cases should be longer (*start-to-finish* is best) to demonstrate operator technique with teaching points. Please plan to transmit only 1 or 2 cases (depending on content) per 60 minute segment. All Coronary Theatre cases are "thematic"; and as such, all cases should adhere to the case theme for the particular transmission segment (please refer to the schedule).

<u>The How-To-Treat Endovascular/Structural Heart Disease Theater</u> - *This is an exclusive venue for endovascular (non-coronary) and structural heart disease (adult congenital and valvular heart disease) cases emphasizing operator technique and thoughtful decisionmaking.* Select complex cases and employ devices and techniques that are available to all practicing Interventionalists. Cases should be longer (*start-to-finish* is best) to demonstrate operator technique teaching points and plan only 1 case (depending on content) per 45 minute segment. All cases are "thematic"; and as such all cases should adhere to the case theme for the particular transmission segment (please refer to the schedule).

As we organize the live case transmissions for TCT, we attempt to consider the special expertise of each of the sites and operators with regard to thematic case content and preferred transmission venues (e.g. Coronary vs. Endovascular/Structural Theater). If for any reason you believe that your site will be unable to complete the assigned thematic case, please contact us immediately so that we can discuss alternatives and schedule modifications.

**No Mini-Lectures** – We have learned from past experiences that brief lectures given from transmission sites diminish the educational experience of the live case format and consume too much precious transmission time. Therefore, we insist that **no lectures** be given from the sites. However, we do strongly encourage that you send us supporting educational materials that can be shown at the conference center (using a side screen) as part of the case presentation. These supporting materials – either PowerPoint slides or videos – should be sent at the earliest possible time to Drs. Giora Weisz and Martin Leon. <u>Under special circumstances</u>, we may agree to show 1-3 slides or a very short video from the transmission site, but this must be discussed before the transmission and pre-approved.

*No Commercial Logos* – TCT is a closely-scrutinized meeting. It is critical that all sites strictly adherence to appropriate policies to minimize any commercial displays that are not solely for educational purposes. Your site must eliminate any perception of commercialism from the transmissions and avoid any displays of products that could be interpreted as commercialization. Adherence to this policy to minimize any commercial displays that are not solely for educational purposes is mandatory. Prohibited displays include corporate logos of any type including, but not limited to scrub hats or thyroid collars that have been supplied by a specific company and that contain that company's logo.

*Conflicts of Interest* – Recently, there has been a deliberate effort to identify and declare any conflicts of interest or relationship with industry concerning devices that are used during live case transmissions. Live case operators are TCT faculty and are subject to all Conflict of Interest disclosure policies:

- All conflicts of interest as they apply to any devices used during the live cases transmitted from your site must be disclosed.
- A TCT Conflict of Interest declaration and resolution form must be completed for every live case operator. <u>This is an absolute requirement for all participating TCT live</u> <u>case operators</u>, not just the primary operator. These will be reviewed by the CME committee of the Cardiovascular Research Foundation.
- Relationships with industry should not in any way influence decisions regarding case selection or device choice.
- These disclosures will be published and will be open to public scrutiny as part of the distributed TCT materials.

#### **Operator Conduct** –

- The highest ethical standards of conduct must be strictly followed. This in part requires that all case operators declare their personal conflicts of interest and fulfill other institutional case presentation requirements (such as special consent forms, appropriate FDA approvals for US operators, HIPPA documents, and video telecast consents from patients).
  - Adherence to the strict and appropriate HIPAA regulations that respect and protect patient confidentiality is required. All forms must be completed and returned immediately after TCT.
  - Code of conduct also refers to the professional manner in which all live case operators (primary and otherwise) conduct themselves throughout the entire live case transmission. This professionalism applies to the opening video and extends to the way in which operators "converse" with each other and with the TCT audience during transmission. Everyone appreciates a friendly and relaxed atmosphere in making these transmissions enjoyable, but "crassness" or inappropriate comments must be avoided. Please be aware that the lay press will be in the audience. In the past, humorous off-hand comments have been reported in very prominent publications and, when taken out of context, have reflected negatively on live case transmissions in general and TCT in particular. Examples of inappropriate comments include mentioning that a specific device is used because it is reimbursed or because that a specific procedure is being performed because it fits into the theme of the particular session.

#### **Case Operator Guidelines**

**Patient safety should always be the primary concern!** Nothing associated with the live case transmission should in any way compromise patient safety. For example, unwarranted delays during the procedure can be avoided with careful planning. The TCT live case transmission times are precise, and live cases must be carefully coordinated to synchronize with these scheduled transmission times.

It is very important that patients not be exposed to excess radiation or contrast media due to the live case format.

Similarly, a live case operator performing the procedure should not spend undue time presenting the case history or answering moderator questions. A second operator should always be available to present the case history and answer questions so that the primary operator can focus his/her entire attention to critical aspects of the procedure.

**Moderator-driven discussions** – There will be active communication between the live case site and the TCT venue that will be driven by experienced live case moderators. The role of the moderator is to make appropriate queries to the operators regarding case strategy and techniques, engage the panel discussants in a lively dialogue concerning relevant case-related topics, and educate the audience regarding important lessons and take-home messages. The experienced moderators and panel discussants will often make suggestions about strategy alternatives and help to interpret ongoing case events. Operators should not feel obligated to alter case strategy based upon moderator or panel suggestions. Nevertheless, there have been many times during live case transmissions where the assistance of moderators or panelists has provided useful input resulting in improved patient outcomes.

Professional and ethical conduct is required of all personnel involved in live case transmissions (including panel moderators and discussants). In the excitement of live case demonstrations, operators and/or panel moderators/discussants are prone to spontaneous comments that can be misinterpreted by the heterogeneous audience at TCT including the lay press. Patient confidentiality and privacy must always be secured! Humorous comments and references to commercial products should be avoided. The atmosphere should at all times be serious, professional, and educational.

**Backup Cases** - We have found that it's always a good idea to have "backup cases," should your primary case(s) become unacceptable for transmission on or immediately prior to the day of transmission. Prior to TCT we will query your site regarding planned cases for transmission, including backup cases. Frequent communication of proposed cases is crucial to plan a coherent overall live case transmission schedule and avoid redundancy or commercial imbalance.

**Operator Tips** – Although all of the sites have experienced and charismatic interventional operators, we have learned several tips to insure maximal educational value during a case transmission. From time to time, we will share these ideas for your consideration. For instance, we believe that there should always be two experienced operators per case. While the "first" operator performs most of the hands-on work, the "second" operator provides the narrative and answers the moderator questions. This maximizes the educational content while ensuring that patient care and safety are optimal.

**Management of Complications** – Not infrequently a procedural complication may arise during a live case transmission. This is especially true due to the high complexity of cases often selected by site operators. It is crucial that any complication during a live case that requires special or urgent attention should not be the subject for discussion or debate and is usually best managed "off camera." It is the responsibility of the case operator or the moderator to advise the audience that the situation requires focused attention and the live portion of the transmission will be truncated (or transitioned to another ongoing live case) until the complication is stabilized.

Of course, this presupposes good judgment from all parties; minor complications, such as a nonflow limiting dissection or a newly occluded sidebranch, can be managed in the context of a continued live transmission, often with important educational value. **At all times, patient safety takes precedence over the educational activity.** 

Also, it is very important to discuss what actions should be taken by the video producer and technicians during a complication. This is to ensure all attention be focused on treating the patient should such an event occur. Although every situation is different, some simple issues need to be addressed in a short amount of time:

- Video equipment cameras, lights, etc. should be moved, dismantled, removed or secured to allow for incoming medical teams of services.
- Microphones and other equipment should be removed from the doctor(s) as the situation permits.
- "Extraneous" video technicians those who have vacated the lab should have an area designated in which to wait. This is to keep them out of the way as much as possible.

This course of action should be reviewed with the video producer and team *in advance* of the transmission. A simple plan on "what to do" would be VERY appreciated by all video technicians.

#### **Patient Rights**

A Sacred Responsibility – Patients who have agreed to be included in live case transmissions at TCT deserve our deepest respect and should be applauded for assisting with our educational mission. At the same time, all aspects of patient rights must be upheld to the highest standards. Careful attention to special informed consents for the live case transmission, adherence to HIPAA regulations, strict maintenance of patient anonymity, and meticulous attention to protect patient safety during the procedures are mandatory for the TCT live case transmissions.

#### **Transmission Paths and Projection Screens**

All feeds coming into the Convention Center appear first in the Master Control Room. All video and audio signals are quality checked and adjusted before being distributed to each of the three venues. Master Control has the ability to receive up to 10 independent video feeds and 60 audio feeds at any given time.

In the control room there will be a video team, audio team, and associate producers – who will coordinate with each site – a transmission director and a Master Control director. The associate producers are well versed in the broadcast vernacular. If a problem occurs anywhere along the transmission path, the Master Control staff will quickly track it down.

All communications between the session moderators - in either the Main Arena, Coronary Theatre or Endovascular/Structural Theatres - and the doctors at the transmission sites will be relayed through the associate producers. These communications include start and stop times, technical issues or other communications needed during the transmission.

#### Transmission

TCT 2013 will coordinate and pay for all transmission paths from each Transmission site's designated video control location to the Master Control Room at the Convention Center. This includes both satellite and fiber-optic based transmissions.

Engineers working for TCT will contact and coordinate with the in-house engineering staffs at each transmission site to ensure a clean signal path from the building and to the transmission service – which will be either satellite of fiber optics.

#### Hard or Soft "Outs"

All sites connecting via satellite (and some with fiber) will be booked with "hard outs." This means there is a specific transmission end time that cannot be extended. <u>With the added complexity</u> and cost of transmitting in HDTV, all "outs" will be strictly enforced.

#### The Big Screen(s) of TCT 2013

All sites will transmit a single video and up to four audio feeds into TCT 2013. To help improve the quality of the live case transmission, it is necessary that all sites utilize video production switchers with a "Picture-in-Picture" effect feature.

Picture-in-Picture ("PIP") is a video production feature that is very helpful in single screen presentations. It allows two images to be displayed on the screen at any one time. A common situation in which to use PIP is when it is helpful to see both live fluoroscopy and the doctor's hands at the same time.

#### Scan-conversion

In order to keep the quality of medical images as high as possible, each site is encouraged to use high quality, new technology computer scan-converters where needed. For images requiring a high degree of detail (fluoroscopy, roadmaps, and 3D renderings) <u>scan-converters similar to</u> the Barco (Folsom) ImagePro HD or 3G are highly recommended.

In any situation, it is a <u>VERY</u> good idea to have each Transmission site's medical imaging provider(s) get involved in the TCT 2013 live case production as soon as possible.

Scan converters or direct video output should be used to show additional video images such as IVUS, OCT, FFR, NIRS, TTE, TEE, etc. These images should not be shown by pointing a camera at the video screen of the specific imaging device console; images recorded and transmitted in this manner tend to be inferior in quality and, at times, interpretable.

Therefore, it is important to get the medical imaging manufacturer(s) technicians – Siemens, Philips, Volcano, etc. – at each transmission site involved in the production as early as possible. The technician can designate a video out from the imaging system or – given enough time – and create an output as needed.

#### **Production Timeline for TCT 2013**

June 29, 2013

#### Letters of Agreement, Contracts and First Invoices Are Due

Invoices should be sent to the Cardiovascular Research Foundation, to the attention of Lizette Rivera- contact information pg. 18.

#### October 15, 2013

#### **Opening Videos and Second Invoices Are Due**

- Opening videos should be sent to Robert Langford *contact information pg. 18.* Videos can be in submitted via FTP download or as a data file on a CD or DVD.
   i. The best format for the data file is the Apple ProRes 422 QT format.
- Invoices should be sent to the Cardiovascular Research Foundation, to the attention of Lizette Rivera

#### October 21, 2013

#### **Patient History Slides Are Due**

Completed patient history slides, planned strategy and device list can be sent via e-mail to Dr. Giora Weisz – <u>tctlivecases@crf.org</u>

#### November 21, 2013

#### **Final Invoices Are Due**

- This will be the final invoice. Any changes or approved additions to the budgets should be presented at this time.
- > All invoices should be sent to Lizette Rivera, <a href="https://www.lizette.nvoices.com">lizette.nvoices.com</a> should be sent to Lizette Rivera.

#### **Primary Points of Contact for TCT 2013**

#### Live Case Content

For issues and questions related to case content, please contact the following:

#### Dr. Martin B. Leon

Cardiovascular Research Foundation 111 East 59th Street 11th Floor New York, NY 10022-1202 USA E-mail: <u>mleon@crf.org</u>

#### Dr. Gregg W. Stone

Cardiovascular Research Foundation 111 East 59th Street 11th Floor New York, NY 10022-1202 USA E-mail: <u>gstone@crf.org</u>

#### Dr. Giora Weisz

Cardiovascular Research Foundation 111 East 59th Street 11th Floor New York, NY 10022-1202 USA Office: +1(212) 305-7060 E-mail: <u>gw2128@columbia.edu</u> **E-mailing slides and device list:** <u>tctlivecases@crf.org</u>

#### **Opening Videos, Technical and Transmission Issues**

Issues pertaining to the technical aspects of TCT 2013 should be addressed to:

#### Robert Langford

Director of Media Services TCT 2013 3102 Borge Street Oakton, VA 22124-2807 USA Office: +1(703) 934-7015 Fax: +1(703) 934-7016 E-mail: medscene@cox.net

#### **Completed Contracts, Invoices, and Official Printed Materials**

All completed contracts and itemized invoices should be sent to the following:

#### Lizette Rivera

Meeting Planning Coordinator Cardiovascular Research Foundation 111 East 59<sup>th</sup> Street 11<sup>th</sup> Floor New York, NY 10022 USA Office: +1(646) 434-4391 Fax: +1(646) 434-4713 E-mail: Irivera@crf.org

#### Faculty related, Non-Technical Questions, and All Other Issues

Should be directed to:

#### Denise Tong Programs Coordinator Cardiovascular Research Foundation 111 East 59th Street 11th Floor New York, NY 10022-1202 USA Office: +1(646) 434-4501 Fax: +1(646) 434-4713 E-mail: dtong@crf.org

#### Clinical History Slides, Planned Strategy, and List of Devices

Should be directed to:

Dr. Giora Weisz Cardiovascular Research Foundation 111 East 59th Street 11th Floor New York, NY 10022-1202 USA Office: +1(212) 305-7060 E-mail: tctlivecases@crf.org

## Appendix A - TCT 2013 Guide to Completing the Transmission Site Production Agreement

Every Transmission site for TCT 2013 must have a signed "**Transmission Site Production Agreement**" with the Cardiovascular Research Foundation. <u>There can be no exceptions.</u>

The agreement covers several legal areas; the two most important are:

- The terms of the business relationship between the Cardiovascular Research Foundation and the Transmission site
- The rules regarding patient confidentiality and releases

The following is a step-by-step guide to completing the Transmission Site Production Agreement. Most of the process is accomplished electronically, with a heavy reliance on the use of e-mail.

Step #1 – As soon as possible, each site should review the draft of the Transmission Site Production Agreement. The agreement covers many issues, so a detailed review is necessary. Also, the agreement has been changed slightly from previous versions, so should be reviewed again by sites familiar with TCT.

If there are any questions as to the content of the agreement, please contact <u>Lizette</u> <u>Rivera</u> immediately.

Step #2 – Complete a Rough Draft of the Agreement. <u>Do this electronically!</u> There are five areas that need information:

**Page 1** - Fill in the blank area requesting information about the transmission site. This includes the company name and legal business address.

**Page 11** – Provide the transmission site's facility name, primary point of contact, and contact information. All mailings and correspondence will be sent to the contact whose information is provided in this area.

**Page 13** – On the signature page, provide the name and title of the site's signatory.

**Exhibit A** – Provide a description of services. A list of minimum production requirements has been provided on this page as a guide to developing a budget. The site's actual production details can be substituted for this text when completing this agreement with the understanding that the substituted production details fulfill all the specified minimum requirements.

**Exhibit B** – "Authorization to Use and Disclose Protected Health Information" Release form. Every patient whose case will be presented at TCT 2013 <u>MUST</u> complete this document – <u>there can be not exception</u>. These forms are due as soon as they can be completed by the patient. Each Transmission site should retain a copy of the release, with the original being sent to the Cardiovascular Research Foundation as soon as possible.

**Exhibit C** – In the box next to the text: "Total Compensation for the Provision of the Services:" fill in the total amount – converted, and in United States dollars only – of compensation for the services described in **Exhibit A**.

[Note: An itemized budget from every site is required as a separate document.]

## Step #3 – Submit the completed rough draft of the agreement – <u>via e-mail</u> - to Lizette Rivera

Do not print and/or sign the *rough draft* document! By submitting the document electronically via e-mail, the review and addressing of issues is expedited.

- Step #4 The rough draft will be reviewed by the legal department of the Cardiovascular Research Foundation. Any issues brought by the transmission site will be discussed, and negotiated changes may be made to the agreement.
- Step #5 An updated draft of the agreement will be e-mailed back to the Transmission site for review. If the updated draft is acceptable, then notify Lizette Rivera. The process then moves onto Step #6
  - A) If there still are questions or issues with the updated draft, notify Lizette Rivera. The agreement will go through another round of discussion to address any remaining issues.
  - B) Any mutually agreed upon changes will be made to the agreement in a new updated draft (Version 2).
  - C) Version 2 of the updated draft will be <u>e-mailed</u> to the transmission site for final review. If the update draft (Version 2) is acceptable, the process will move onto Step #6.
  - D) If not, then repeat Steps 5A thru 5C until a mutually accepted agreement is reached.
- Step #6 The accepted, updated draft of the agreement will be converted into an electronic "PDF" document by the legal department of the Cardiovascular Research Foundation. This PDF document will be e-mailed to the transmission site.
- Step #7 <u>At this point</u>, the transmission site will print two copies of the PDF file of the final agreed upon version of the Transmission Site Production Agreement. After printing two copies, the site should:
  - A) Sign both copies,
  - B) "FedEx" both *signed* copies to the Cardiovascular Research Foundation
  - C) The signatories at the Cardiovascular Research Foundation will sign both copies
  - **D)** The Cardiovascular Research Foundation will "FedEx" the transmission site's mutually signed copy **to the address provided on Page 10 of the agreement.**

At the end of this process, the Transmission Site and the Cardiovascular Research Foundation will have mutually signed copies of the agreement.

Most of the process will be handled via e-mail. If there is a problem accessing e-mail, please notify Lizette Rivera immediately.

TCT 2013 Overview of Live Case Transmission Schedule					
Day 1, Tuesday Oct 29					
Time (PDT)	Main Arena	Coronary Theater	Endo / Structural Theaters		
8:00 AM	Bonn, Germany (Grube)	Lectures	Lectures		
8:30 AM		Columbia, NY	Quebec, CA		
8:45 AM	Sao Paulo, Brazil (Abizaid)				
9:00 AM					
9:30 AM	Late Breaking Trials	Bonn, Germany	Columbia, NY		
10:00 AM					
10:30 AM		Lectures	Lectures		
11:00 AM	Quebec, CA (Rodes-Cabau)	Sao Paulo, Brazil	Bonn, Germany		
11:30 AM					
12:00 PM		Quebec, CA	Sao Paulo, Brazil		
12:15 PM	Columbia, NY				
12:30 PM					
1:00 PM	Closed	Closed	Closed		
1:30 PM					
2:00 PM					
2:30 PM					
3:00 PM					
3:30 PM					
4:00 PM					
4:30 PM					
5:00 PM					

### Appendix B – Live Case Schedule (Subject to changes)

Day 2, Wednesday, October 30				
	Main Arena	Coronary Theater	Endo / Structural Theaters	
8:00 AM	Tel Aviv, Israel (Banai)	Lectures	Lectures	
8:30 AM		Columbia, NY	Leipzig, Germany (Schienert)	
8:45 AM	London, UK (Thomas)			
9:00 AM				
9:30 AM	Late Breaking Trials	Tel Aviv, Israel	Baptist, FL (Katzen)	
10:00 AM				
10:30 AM		Lectures	Lectures	
11:00 AM		London, UK	Leipzig, Germany	
11:30 AM	Cedars-Sinai, CA (Makkar)			
12:00 PM		Cedars Sinai, CA	Columbia, NY	
12:15 PM	Baptist, FK (Katzen)			
12:30 PM				
1:00 PM	closed for lunch	First Reports	First Reports	
1:30 PM				
2:00 PM	Annivarsy lect and panel			
2:30 PM		Lectures	Lectures	
3:00 PM		Taipai, Taiwan (Kao)	UC Davis, CA (Laird)	
3:30 PM				
4:00 PM		Taipai, Taiwan	UC Davis, CA	
4:30 PM				
5:00 PM				

Day 3, Thursday, October 31			
	Main Arena	Coronary Theater	Endo / Structural Theaters
8:00 AM	Antwerp, Belguim (Verheye)	Lectures	Lectures
8:30 AM		Piedmont, GA (Kanzari)	Massy, France
8:45 AM	Vancouver, CA (Webb)		
9:00 AM			
9:30 AM	Late Breaking Trials	Scripps, CA (Teirstein)	Frankfurt, Germany
10:00 AM			
10:30 AM		Lectures	Lectures
11:00 AM		Piedmont, GA	Vancouver, CA
11:30 AM	Massy, France (Morice/Lefevre)		
12:00 PM		Antwerp, Belgium	Scripps, CA
	Frankfurt, Germany (Seivert)		
12:30 PM			
1:00 PM		First Reports	First Reports
1:30 PM			
2:00 PM			
2:30 PM		Lectures	Lectures
3:00 PM		Seoul, Korea (Park)	Rush, IL (Hijazi)
3:30 PM			
4:00 PM			
4:30 PM		Seoul, Korea	Rush, IL
5:00 PM			

Day 4, Friday, November 1					
	Main Arena	Coronary Theater	Endo / Structural Theaters		
8:00 AM	Milan, Italy (Colombo)	Closed	Closed		
8:30 AM					
8:45 AM	Milan, Italy				
9:00 AM					
9:30 AM	Late Breaking Trials				
10:00 AM					
10:30 AM					
11:00 AM	Closing session				
11:30 AM					
12:00 PM					
12:30 PM					