

Notes from the Southern Consortium Node

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As usual, it has been a busy and productive time for the Southern Consortium. In addition to our usual stellar participation in on-going CTN projects, we are doing our best to get some new Southern Consortium-led studies going.

At our retreat in June, we identified a number of promising areas for concept development. These included new medication treatments, innovative psychotherapeutic treatments and the adoption of technology to improve treatment delivery.

We formed work groups to focus on each of the concepts and following the retreat, these groups have been busy developing and focusing their concepts. We have made some remarkable progress!!!

One of my work groups submitted a concept to study a new medication that works on the glutamate neurotransmitter system, n-acetylcysteine, in the treatment of marijuana dependence. This project got a favorable review by the Research Development Committee (RDC) and we are in the preliminary stages of protocol development. Dr. Therese Killeen submit-

ted a concept to investigate the use of a form of exposure therapy developed at MUSC for the treatment of co-occurring PTSD and cocaine dependence.

This project is currently under review with the RDC. Louise Haynes, in collaboration with a group of investigators from the University of Alabama, submitted a concept to investigate smoking cessation treatment in HIV positive individuals.

Dr. Ashwin Patkar and his work group submitted a concept proposing an investigation of disulfiram (antabuse) in the treatment of cocaine dependence.

These two projects are also under review. Concepts still in development include investigation of the use of mindfulness meditation in the treatment of addictions, a computerized treatment for co-occurring depression and addictions and a computerized Screening, Brief Intervention and Referral for Treatment (SBIRT) that can be delivered in primary care settings. Please let me know if you are interested in work-

ing on any of these concepts. The work groups have all had a nice mix of researchers and community treatment providers.

We are optimistic that we will have success with more than one of these concepts. Thanks to you all for your help with these efforts and everything else that you do to make the Southern Consortium a great success.

Dr. Kathleen Brady
MUSC

North Carolina's New Node Coordinator

Craig McLendon has taken over for Bart Evans as Node Coordinator at the Duke Clinical Research Institute (DCRI). A graduate of University of North Carolina at Greensboro, he has a Bachelor of Science degree in Nursing.

Craig has been at Duke for 21 years. Prior to joining the Duke Clinical Research Institute, he gained extensive experience in critical care nursing, including neonatal ICU, emergency department, cardiothoracic surgery, coronary care, and Lifeflight/Lifecare.

A Project Leader at the DCRI, Craig has vast experience in both government- and industry-sponsored studies in cardiology, otolaryngology and substance abuse, with previous experience on NIDA. He has also led several large international studies enrolling over 20,000 patients in over 50 countries.



Craig McLendon

TROSA Launches Extensive Building Project

Having a clean, safe, sober place to call home is a change for many of the men and women at TROSA. As TROSA's President and CEO Kevin McDonald says, "Treating people with dignity, showing them a better way to live and that they deserve to live this way, is an important first step in their recovery."

This spring TROSA launched an extensive building project -- two new 75 bed dormitories, (one for men and one for women) are being constructed on the James St. campus in Durham, NC. Funding is being provided by a grant from the US Department of Housing and Urban Development, US Department of Veterans Affairs, and a no-interest loan from the North Carolina Finance Agency. "We still need to raise \$300,000 but

we couldn't wait," says Kevin. "Our people need and deserve this housing."

For Mr. William Mack, TROSA's master brick mason, the project means long work days and lots of residents to train. One of the first TROSA graduates and a veteran himself, Mr. Mack is known for his straightforward approach with the members of his brick crew.

Currently, a group of about 15 men are laying brick on the exterior walls. Mr. Mack notes, "A lot of the younger guys have limited experience, but they're working really hard to get this work done." One of his senior crew members, Louis, appreciates the construction and masonry skills, and the intangible



Mr. William Mack mentors a TROSA resident.

ones too. "Mr. Mack has taught me so much, about more than bricks, about being a man." The dorms will be completed by Spring 2012.

TROSA is a two year residential recovery program located in Durham, NC.

Tracey Dryden

SouthLight, Inc. is Awarded a Grant Continuation

SouthLight, Inc. is very pleased to announce that we recently received a two year continuation on our grant from the Kate B. Reynolds Charitable Trust.

This will allow us to continue providing SBIRT services in three primary medical care facilities which serve the indigent population. We have been warmly received by these organizations and their patients during this past fiscal year and have been

able to demonstrate positive outcomes for this project.

As part of our commitment to enhance and expand the mental health services at our various SouthLight sites, we will begin offering a specialized group for individuals who have been diagnosed with anxiety and its related disorders.

The first group will begin at our Garner Road location beginning in

September and will be implemented at our other sites as clients are identified. In addition, SouthLight plans to develop specialized groups for those individuals who have been diagnosed with depressive disorders and PTSD.

*Ernestine Chapman, MS, LPC, LCAS, CCS
Director of Clinical Services
SouthLight, Inc.*

Mobile RA Joins the LRADAC Team

The LRADAC CTN0046 team would like to send a "BIG" welcome to Beatrice Koon, our newest Research Assistant (RA).

While Beatrice is new to our team, she is not new to the CTN or the Southern Consortium. Beatrice has had the unique opportunity to experience the CTN in several different settings.

She began her CTN career as a RA Counselor on the CTN 0032 study at Morris Village Alcohol and Drug



Beatrice Koon and Beverly Holmes

Addiction Treatment Center in Columbia. She then transitioned to the Project AWARE study at the

Richland County Health Department with employment through the University of South Carolina. We are very fortunate to have her to continue in the CTN on our LRADAC team.

Beatrice brings energy, creativity and enthusiasm with her to our team. She is currently working on her Master of Social Work degree at Winthrop University in Rock Hill, SC.

Beverly Holmes

The Atlanta VA has a Research Pharmacist

Several clinical trials conducted by the Southern Consortium have been medication trials. For most of those studies, the research staff (study clinician or research coordinator/assistant) have been responsible for all study drug accountability.

However, research staff for the CURB study at the Atlanta VA will not have to manage drug accountability alone. They are fortunate to have Dr. Mehran Salles, research pharmacist, to facilitate the management of all study medication required to con-

duct the study.

Her office will be responsible for the receipt and preparation of all medication from the study's central pharmacy and the purchase of all other required medications.

The medications will be requested for administration to study participants by the research staff as needed. Dr. Salles will be working closely with the research staff to ensure all medication, especially the Schedule III medication (Suboxone), is

stored securely and managed accurately at the research office.

She is a great asset to this team who are all working hard to prepare for implementation of the CURB study. The team is very eager to get started.

Kimberly Pressley
CURB Project Manager



Pictured Left: Dr. Mehran Salles (Research Pharmacist); Pictured Right: Dr. Rachel Holt (Therapist), Stephanie Raines (Research Assistant), Karen Blackburn (Nurse Practitioner), Dr. Karen Drexler (Site Principal Investigator), Antoinette Gamble (Nurse Practitioner), Ylba Hooker (Nurse), and Dr. Richard Amar (Physician).

SATTC Appoints New Program Manager

With his recent appointment as the Southeast ATTC, North Carolina Program Manager, Michael Bridges is looking forward to working closely with the Southern Consortium Node of the CTN to facilitate providing training to front-line staff that is evidenced based. He is very excited about playing a supportive role with the SCN Staff at Duke and the North Carolina CTPs to make the results of their work part of the professional development of current and future substance abuse clinicians.

Michael received his undergraduate degree from Saint Augustine College and his graduate degree from Webster University. A skilled trainer, Licensed Clinical Addictions Specialist (LCAS), and a Certified Clinical Supervisor (CCS). His specialty area is working with the "hard to engage" clientele and has been in the field of addictions for 15 years.

He is the owner of A New Start Support Services II, LLC; a private agency that delivers a list of services for both adolescents and

adults. These services include DWI treatment, individual and group therapy, anger management, Substance Abuse Intensive Outpatient Treatment (SAIOP), Substance Abuse Comprehensive Outpatient Treatment (SACOT), Gender Responsive Treatment (GRT), and Gambling Addiction.

The practice has a consulting division that provides training and support to community based agencies. The mission of the training division is to focus on "best practices" on how services can be delivered to ensure greater outcomes in regard to client retention, quality of service delivery, and treatment outcomes.

Prior to working in the private sector, he was employed with the North Carolina Department of Correction (NC DOC), Division of Alcoholism and Chemical Dependency Programs (DACDP) as a Clinical Trainer. His primary job function was to research, develop, design, and deliver clinical training material to enhance the expertise of the clinical counseling staff with-

in the department. A secondary job function was to educate outside governmental and educational systems about addiction. He has had the opportunity to train at UNC's School of Government for the Judicial College Program and the North Carolina Drug Courts.

Prior to coming to the NC DOC, he spent 3 years as a Substance Abuse Counselor at SouthLight, Inc. as well as three years with Wake County Human Services in Raleigh, NC.

Ed Johnson
South Carolina Program Manager,
Southeast ATTC

Coastal Horizons News

Our CTP, Coastal Horizons Center, has been in operation as a private non-profit since 1970 based out of Wilmington, North Carolina. Since then, we have evolved into a multi-service agency delivering critical services such as outpatient substance use disorder and mental health treatment to residents of the New Hanover, Pender and Brunswick counties.

We also offer Opioid Replacement Therapy, HIV Early Intervention, regional Prevention and Outdoor Adventure programs, Crisis Intervention Services (including Rape Crisis, Crisis Line & First Call for Help Hotlines, and Open House Emergency Youth Shelter and Services), regional TASC / Criminal Justice Services, and the statewide

NC TASC Training Institute.

Over the past couple of months, we have participated in the CTN-0051 Treatment Setting Snapshot Survey, interviewing with research staff from the University of Georgia.

We have also completed our first year of primary care integration, utilizing a Nurse Practitioner to provide “reverse co-location” services to our patient population who are also receiving substance use disorder treatment services on an outpatient basis.

During this year, we saw 167 patients and administered 81 flu vaccines. The majority of those patients had never before received

a flu vaccine. The most prevalent issues from this population were hypertension, diabetes, and hyperlipidemia (elevated cholesterol).

Kenny House, LCAS, CCS
Clinical Director

New Director Appointed at SCN Collaborator DAODAS

The SC Department of Alcohol and Other Drug Abuse Services (DAODAS), a frequent collaborator with the Southern Consortium, is looking toward the future under the leadership of new director Bob Toomey, who was appointed by Governor Nikki Haley earlier this year.

After working in critical state government roles for many years, Toomey retired from the State in 2002, but is excited about his return and the opportunity to provide direction for South Carolina's statewide system of community-based substance abuse agencies.

In an effort to familiarize himself with the efforts and needs of the state's service providers, earlier this year Toomey embarked on a listening tour of local and regional agencies, which included a visit with staff of the Southern Consortium.

During this meeting, he shared his plans – in concert with the SC Department of Health and Human Services – to provide Screening, Brief Intervention, and Referral to Treatment (SBIRT) for Medicaid beneficiaries who are pregnant. He

also discussed ways that DAODAS and the Southern Consortium could collaborate and connect the CTN's research efforts to improvements in state-supported services.

In addition to his years of professional experience, Toomey has been an active volunteer in the area of behavioral health, serving as Board Chair for the Mental Health Association in South Carolina and a member of the National Alliance on Mental Illness and Faces and Voices of Recovery South Carolina, among other service organizations.



Bob Toomey

Recruitment and Retention

LRADAC Offers Innovative Tips for Retention

LRADAC is a participating site on the CTN-0046 study. The study's three specific retention goals include: treatment completion, 3 month, and 6 month follow-ups. LRADAC has maintained 100% on all three retention goals thus far. We partly contribute this success to the rapport that is instantly built with clients.

Our CTN staff ensures a welcoming environment the first time we meet clients by always having a genuine and friendly demeanor and by taking time to say something positive.

Once a client becomes a participant, we believe it is important for all CTN

staff to interact with them, thereby, making the participant comfortable with all team members.

We also take a few minutes to debrief after seeing each client; this allows us to be on the same page with the progress of each participant. We believe it is essential to be an attentive listener so that we can reflect on comments or stories that the clients have shared previously.

We find that the clients are amazed that we remember information from weeks ago, whether it is minor or significant. This shows

the client that what they have to say is important to us.

When speaking with clients about returning for their follow-ups, we are clear that no matter what is going on in their lives, we still want to see them because what they bring to the study is important. LRADAC believes these seemingly insignificant details are as important as having great contacts in increasing retention rates among study participants.

*Beverly Holmes
Beatrice Koon*

S-CAST Recruitment Tools and Methods

Recruitment is a critical component of a successful trial. Every study sets forth a goal that we as researchers strive to achieve. Unfortunately, there are times we fall short. I hope to help you keep recruitment in the forefront of your mind to avoid not reaching those goals.

Different studies require different recruitment methods, but every recruitment tool must be IRB approved. For example, we purchase yard signs to place them throughout the community and in the agency windows. We also print flyers to hand to each new adult client as well as having them strategically placed throughout the agency.

In order to successfully recruit, the entire clinical staff should be aware of the study. We always schedule a luncheon with our PI to explain the study to all staff. This will hopefully establish clinical buy in. We also offer an incentive for the clinicians where they can have their name in a monthly drawing for sending referrals.

Getting the word out is vital so we



Recruitment sign in the window of BHSPC

Reevaluate your methods and brainstorm for new ideas if you aren't meeting your goals. Always remember that being proactive helps to eliminate not achieving satisfactory performance. Happy recruiting fellow researchers!

*B. Elizabeth Chapman,, BS, CACII
Director of Research
CTN-0030, CTN-0046*

schedule presentations with community providers and clients as well as giving something tangible like a pen or pad with the research phone number.

With our current study, CTN-0046, S-CAST, our participants have to be in services at our agency so our recruitment pool is smaller. We utilize the above tools as well as handing out the study brochures. Another effective procedure coined as Respondent Driven Sampling (RDS) is where your participants receive an incentive for sending referrals. We also have a monthly drawing for non-participants who send referrals.

"In order to successfully recruit, the entire clinical staff should be aware of the study.

STRIDE Teams Complete Node's First Successful Patient Transfer

When a participant at the Charleston VA site of the CTN-0037 STRIDE protocol unexpectedly moved two hours away after completing just 3 weeks of this 37 week trial, it seemed like his participation in the study intervention would have to end. Unfortunately, when a participant moves away from the study site, barriers of travel and time constraints make continued participation difficult.

Since the participant was interested in continuing participation despite the move, one option allowed by the STRIDE protocol was to continue assessments by phone. However, this would not allow the participant to continue receiving the study intervention, which involves exercising on a treadmill at the study site.

The Charleston VA staff then realized that the participant, who had moved to Columbia, was now located only a few miles away from another SC Node STRIDE study site located at Morris Village. Though it had not previously been done in this protocol, or in any other protocols conducted within the SC node, the VA decided to look into the possibility of having the participant resume study procedures at Morris Village.

After discussion with the Node PI

and Protocol Manager, several steps were taken to determine if the transfer of the participant was possible. First, the STRIDE lead team was contacted about the idea. The lead team was very excited about the possibility of having this participant continue in the study and gave the "OK" to proceed with the transfer. The IRBs involved in oversight of both sites were then contacted to see if any additional review would be necessary for the transfer to occur.

It was also important to ensure that site specific policies were followed during the transition process; for example, Morris Village had special requirements for allowing a non-patient on to the grounds of the treatment facility.

The most important step to the successful transfer of the participant was communication between the two sites. Prior to the transfer, the sites had a conference call to discuss specifics of the patient's participation, the transfer of the participant's files, and how communication with the participant would be handled.

The VA staff did an excellent job of keeping the participant engaged in the study while approvals were sought and the transfer process

finalized. The Morris Village staff went above and beyond in taking on this new participant and welcoming him to their site. Both sites were sure to carefully document the transfer process in their study files.

Because of the hard work and quick thinking on the part of both sites, this participant will be able to fully continue his study participation. Though the transfer of a participant from one site to another may not be feasible for all protocols, it may be an option for other sites, along with their protocol lead team and RRTC staff, to consider.

Congratulations to the Charleston VA and Morris Village sites on the successful transfer of this participant, a first for the Node!

Erin Klintworth

Promoting Awareness of Motivational Incentives (PAMI)

Motivational Incentives (also known as contingency management) are a supplement to other therapeutic modalities in the treatment of substance use disorders. Motivational Incentives (MI) have been shown by over 30 years of research to be an effective strategy in their treatment.

PAMI training is provided to assist the translation of research findings into practice at clinical sites by frontline service providers. This

training is one of NIDA/SAMHSA's Blending Product Initiatives and is delivered to enhance treatment outcomes and facilitate patient recovery from substance use disorders.

Alice Petersen, Program Manager at the Duke Clinical Research Institute, recently completed PAMI training for new trainers. Plans are in the works for Alice to co-deliver PAMI training with Beverly Holmes from LRADAC in South

Carolina, with the ultimate goal of making PAMI training readily available in North Carolina. If your North Carolina CTP or other local entity would be interested in receiving PAMI training, please contact Alice Petersen at 919-668-8091 or alice.petersen@duke.edu.

"PAMI training is provided to assist the translation of research findings into practice at clinical sites by frontline service providers."

Upcoming Dissemination / Training Events

Conferences

November 10-11 "Uniting Soul and Role: Creating Transformational Leadership in Addiction Treatment and Recovery" 2010 Carolinas Conference on Addiction and Recovery, Morganton, NC: A panel of CTP representatives will be sharing their experiences with adopting and implementing evidence based practices

November 13, 14 and 15. "The Science of Recovery". 2010 SCAADAC Conference, Wild Dunes Resort, Isle of Palms, SC. On November 15th Susan Sonne, PharmD, BCPP, will be part of a Panel Discussion, "The Changing Landscape of Addiction Treatment and Recovery from a Medical Perspective" from 8:30 -1:00pm

November 30- December 1. SC Drugs of Abuse Conference, Columbia Marriott, Columbia, SC . On November 30, Susan Sonne, PharmD, BCPP will present a concurrent work shop from 2:00 – 3:15pm "Current Trends in the Use of Medication for Addiction Treatment".

Stand Alone Trainings

North Carolina, Paul Nagy, MS, LCAS, CCS, Presenter

South Carolina, Louise Haynes, MSW and Susan Sonne, PharmD, BCPP, Presenters

October 11 – (with DAODAS) "The New Frontier: Medication in the Treatment of Substance use Disorders"
Lexington/Richland Alcohol and Drug Abuse Commission (LRADAC), Columbia, SC

Oct. 5, Nov. 2, Dec 7 - Substance Abuse Best Practices Teaching Case Conference for The Guilford Center, Greensboro, NC

Oct. 12, Nov. 9, Dec. 14 - Substance Abuse Best Practices Teaching Case Conference for The Durham Center, Durham, NC

October 20, November 17 and December 22 - Substance Abuse Best Practices Teaching Case Conference for the Sandhills Center, West End, NC

Sept 9, Oct. 19, Nov. 19, Dec. 21 - Motivational Interviewing Coaching Series for Guilford County Substance Abuse and Mental Health Professionals , Guilford County, NC

Oct. 12, Nov. 9, and Dec. 14 - Motivational Interviewing Coaching Series (Advanced and Beginners) for Durham County Substance Abuse and Mental Health Professionals , Durham County, NC

October 20, November 17 and December 22 - Motivational Interviewing Coaching Series for Sandhills Area Substance Abuse and Mental Health Professionals, Moore County, NC

October 7, 2011 - Intensive Outpatient Treatment of Substance Abuse - The Durham Center/North Carolina Evidence Based Practice Center, Durham County, NC

October 17, 2011 - Group Therapy Skills Training - Southlight Behavioral Health, Raleigh, NC

October 21, 2011 - Evidence Based Relapse Prevention Strategies - The Sandhills Center/The North Carolina Evidence Based Practice Center, Moore County, NC

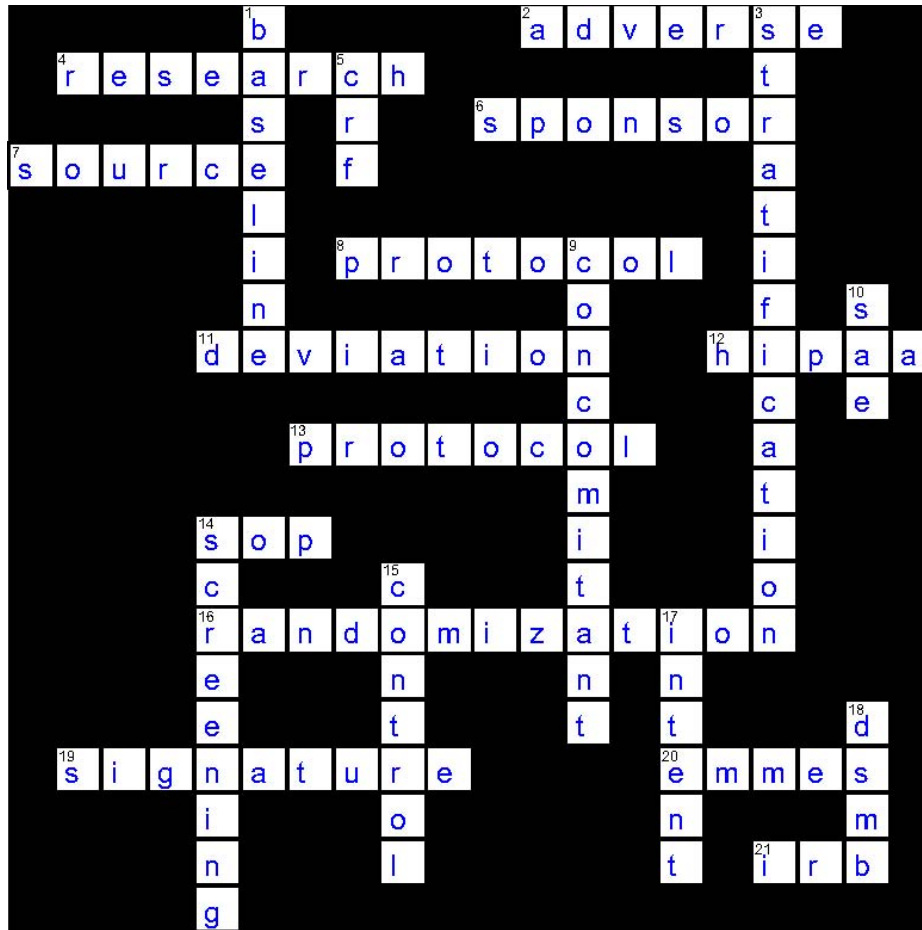
November 11, 2011 - Motivational Interviewing for Advanced Practice Providers - Duke University, Durham, NC

November 18, 2011 - Intensive Outpatient Treatment of Substance Abuse - McLeod Addictive Disease Center, Charlotte, NC

December 1, 2011 - Relapse Prevention Strategies - Greensboro AHEC, Greensboro, NC

December 2, 2011 - Overview of Substance Abuse Treatment Best Practices, Northwest AHEC, Winston-Salem, NC

ANSWER KEY: JUNE 2011 CROSSWORD



Across

- 2 An _____ event is any reaction, side effect, or untoward event that occurs during the course of a clinical trial, whether or not the event is considered study related or clinically significant.
- 4 Systematic investigation designed to develop or contribute to generalized knowledge.
- 6 An organization that manages or finances a clinical trial (e.g. NIDA).
- 7 _____ documents are original documents, data, and records that are used in a clinical trial.
- 8 A document that describes the objective, design, methodology, statistical consideration, and organization of a trial.
- 11 Failure to conduct a study procedure as described in the protocol should be documented as a Protocol _____.
- 12 The first comprehensive federal protection for the privacy of personal health information.
- 13 A document that describes the objective, design, methodology, statistical consideration, and organization of a trial.
- 14 The local _____ provides detailed written instructions to achieve uniformity of procedures at an individual site.
- 16 A method based on chance by which study participants are assigned to different treatment groups.
- 19 The Site _____ Log is a list of individuals authorized to execute specific functions in a study.
- 20 The Coordinating Center for CTN studies.
- 21 A committee that initially approves and periodically reviews the research in order to protect the rights of human participants.

Down

- 1 Initial point in a clinical trial that provides a basis for assessing changes in subsequent assessments or observations.
- 3 Separation of a study cohort into subgroups according to characteristics like age, gender, etc., so that factors which might affect the outcome of the study can be taken into account.
- 5 A document designed to capture protocol-required data for a study.
- 9 _____ medications are prescription and over-the-counter drugs and supplements a study participant has taken along with the study intervention.
- 10 An adverse event that results in inpatient hospitalization would be considered a _____.
- 14 The _____ Log is an essential document that records all individuals who begin the process of determining eligibility for a study.
- 15 The _____ group refers to individuals in a clinical trial assigned to a comparison intervention. This is often called "Treatment as Usual" in CTN studies.
- 17 An _____ to treat analysis includes all data from participants in the groups to which they were randomized.
- 18 An independent committee that reviews data while a clinical trial is in progress to ensure participants are not exposed to undue risk.