VERISTAT

HOW TO BETTER PLAN YOUR VIRTUAL TRIAL – A REVIEW OF LESSONS LEARNED

LIVE WEBINAR | PRESENTED BY SHAHEEN LIMBADA, BRENDA MUSKAT, AMY BOSSONS

A LIVE XTALKS WEBINAR HELD ON 26 MARCH 2021

MEET VERISTAT

Veristat is a scientific-minded global clinical research organization (CRO) that enables sponsors to solve the unique and complex challenges associated with accelerating therapies through clinical development to regulatory approval.

With more than 26 years of experience, Veristat is equipped to support any development program with clinical program planning, trial conduct, navigating the regulatory approval process, and ensuring post-approval safety surveillance.

MEET THE SPEAKERS

Shaheen Limbada

Executive Vice President, Global Clinical Operations, Veristat

- Shaheen has over 20 years of experience conducting clinical trials
- He is a pioneer in rapidly implementing virtual clinical trial strategies into risk management, project management, patient recruitment, clinical study conduct

Brenda Muskat

Global Clinical Project Director, Veristat

- Brenda brings expertise from over 15 years of managing global phase I-IV and NIS clinical trials
- Brenda was a lead on the clinical trials for three FDA approved therapies for Cardiovascular Disease, Cancer and Diabetes

Amy Bossons

Senior Project Manager, Veristat

- Amy is an established Senior Project Manager with 10 years of experience in the CRO setting and CTU setting
- Amy has experience from a Research Network perspective and has spent many years at site level coordinating the delivery of trials

AGENDA

- Defining & Introducing Virtual/Decentralized Trials
- Implementing A Decentralized Clinical Trial Model
  - Challenges & Tips
  - Final Thoughts
- Questions

POLL QUESTION

How many decentralized/virtual trials have you or do you plan to implement?

- None
- 1-2
- 2 or more
- All trials moving forward will have virtual components

THE TIME FOR VIRTUAL TRIALS IS NOW!

THE COVID-19 PANDEMIC IS DRIVING THE RAPID NEED AND ADOPTION OF VIRTUAL TRIALS WHERE PATIENTS ARE TREATED AT THEIR HOMES INSTEAD OF GOING INTO A BRICK/MORTAR SITE

INDUSTRY HAS MANY DEFINITIONS

VIRTUAL TRIALS NOMENCLATURE

- Virtual (Clinical) Trials
- Remote (Clinical) Trials
- Decentralized Trials (DCT)
- At-home Trials
- Clinical Trials at Home
- Clinical Trials from Home
- Home Clinical Trials
- Direct to Patient Trials (DTP)
- Hybrid Virtual Trials

THE VIRTUAL TRIALS CONTINUUM

TRADITIONAL TRIALS

- Patient travels to site for all visits

VIRTUAL TRIALS (HYBRID)

- Patient participates with a combination of at-home and on-site visits

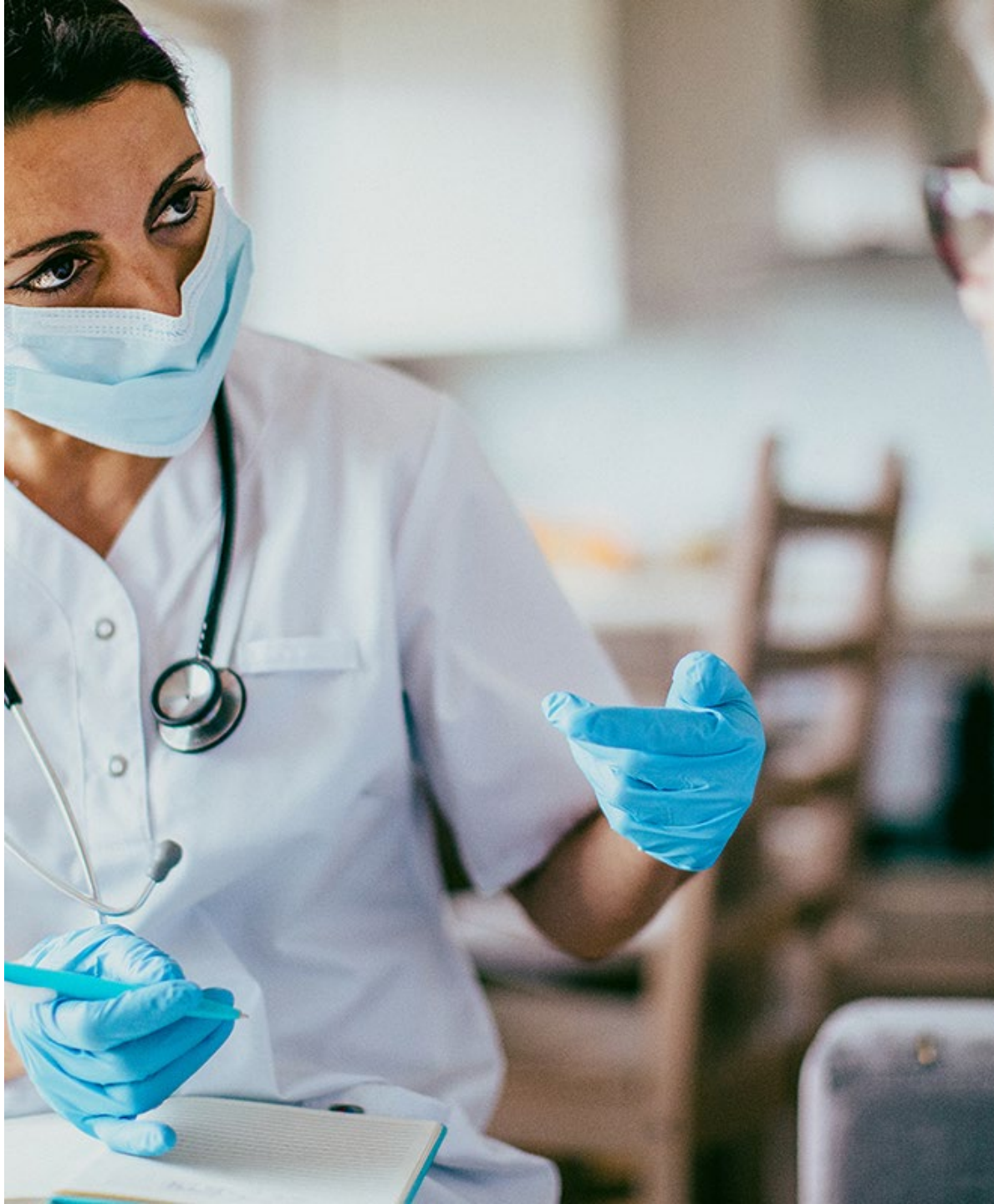
VIRTUAL TRIALS (FULLY)

- Patients participate in trial fully from home
- No on-site visits

THE BENEFITS OF VIRTUAL/DECENTRALIZED TRIALS

- Improves patient-centricity by reducing burden on patients
- Broadens access to patient populations- patient access is less restricted by geography
- Improves flexibility - trials can be customized to be completely virtual decentralized or all onsite.
- Overcomes COVID-19 restrictions for physical access to hospitals/medical facilities/sites

Overall, optimzes a patient focused approach which can lead to trial efficiency and effectiveness.



VERISTAT VIRTUAL/DECENTRALIZED TRIAL OFFERING

Flexible and Customized to the Needs of the Patients and Trial Design

Digital Patient Recruitment/Retention

- Digital marketing and branding strategies for patient and site recruitment and education
- Physician-staffed call center to qualify and register patients
- Communication channels between the site, at-home nurse, patient, and other integrated vendors/technologies

At-Home Patient Visits

- Nurse conducts the at-home patient visits as outlined by the study protocol
- Proven logistics management such as sending supplies to the patient instead of site, facilitating lab work, etc.
- Collection of source data at home

Virtual Patient Interactions

- Connecting patients and treating physicians through Telemedicine (video meetings)
- Utilizing ePRO, eSource, and eConsent capabilities that integrate with EDC
- Monitoring traditional sites and virtual sites remotely

IMPLEMENTING A DECENTRALIZED CLINICAL TRIAL MODEL

Lessons Learned

HOME HEALTH NURSE (HHN) VENDOR SET-UP

CHALLENGES	TIPS TO OVERCOME
Complex protocols-ensuring HHN vendor understanding	Select an HHN vendor who is experienced, specifically in clinical trial research operations
Set up timeframe	Request set up time metrics Pre-empt potential delays For specialized populations and procedures, plan for time to train HHNs
Communication	Have a communication plan, with expectations and responsibilities defined
HHN nurse availability at each site	Provide general patient locations to HHN early Request info about geographic nurse resources
Site acceptance	Provide clear communication of what to expect Have a plan in place for cases where PIs are not willing to sign the Delegation of Authority for the HHN

DOCUMENT AND DATA FLOW

Challenge

HHN **may or may not** be willing to:

- Upload home assessments to central vendors
- Enter data into EDC
- Email source docs
- Complete SAE forms
- Support report filing requirements
- Answer queries in EDC
- Perform ad hoc home visits if the unexpected happens
- Order and ship equipment to subject homes

Tips to Overcome

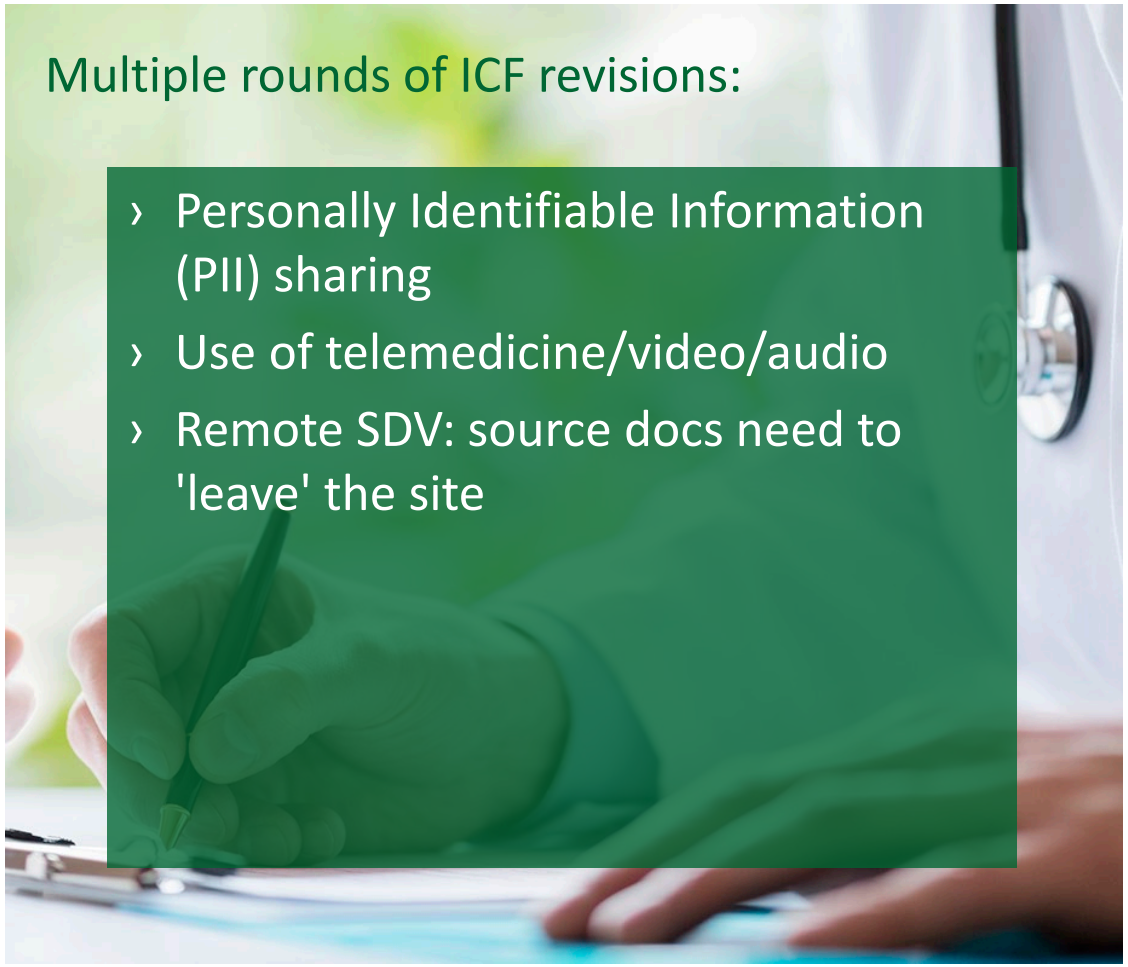
- Utilize e-source tool that links directly to EDC
- Discuss document and data flow in detail during set up
- Clearly inform sites what they will and will not be responsible for, when home visits occur.
- Include 'unscheduled' visits in the HHN contract
- Negotiate with HHN vendor to handle shipments to subject home

PROTOCOL AND SITE BUDGET CONSIDERATIONS

CHALLENGES	TIPS TO OVERCOME
HHN may not be qualified to perform all visit procedures	> Define in your protocol which visits are onsite - mandatory > Outline in protocol which procedures can done by HHN at home, at 'next' site visit by PI or at community medical center > Implement telemedicine to enable PI oversight, and include stipulations for use in protocol > Enable flexibility in study design to move between home visits and site visits
Site payments – duplicate HHN payments	Plan ahead for site budgets: ▪ Visit at home vs. at site --> avoid duplicate payments to HHN and site
Site and subject burden - travel planning and payments (for any mandatory onsite visits)	Move travel planning and reimbursement out of your site level budget by outsourcing to a 3rd party travel vendor

INFORMED CONSENT CONSIDERATIONS

Challenge



Multiple rounds of ICF revisions:

- Personally Identifiable Information (PII) sharing
- Use of telemedicine/video/audio
- Remote SDV: source docs need to 'leave' the site

Tips to Overcome

Include the following language in your Consent:

- Agreement for HHN to enter home
- Provision of PII to courier and HHN
- Inform patient of video/audio details
- If needed, *redacted* source documents will 'leave' the site for the purposes of SDV only
- Sharing of PII with 3rd party travel vendor

OTHER PRACTICAL CONSIDERATIONS

More than one subject in same geography

› Stagger enrollment to avoid need for HHN to be in two places on the same day

Unblinded study drug administration at home

› Identify when more than one HHN may be needed at home visits

COVID-19 travel restrictions when patient safety labs are required

› Implement community lab pre-pay options

FINAL THOUGHTS & RECOMMENDATIONS

- Challenges with nursing groups
- Data collection
- Consent
- Study design

QUESTIONS?

SPEAKER CONTACT INFORMATION

Shaheen Limbada

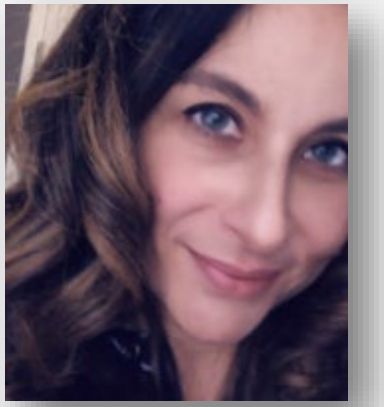
Executive Vice President, Global Clinical Operations, Veristat

Shaheen.limbada@veristat.com

Brenda Muskat

Global Clinical Project Director, Veristat

Brenda.muskat@veristat.com



Amy Bossons

Senior Project Manager, Veristat

Amy.bossons@veristat.com