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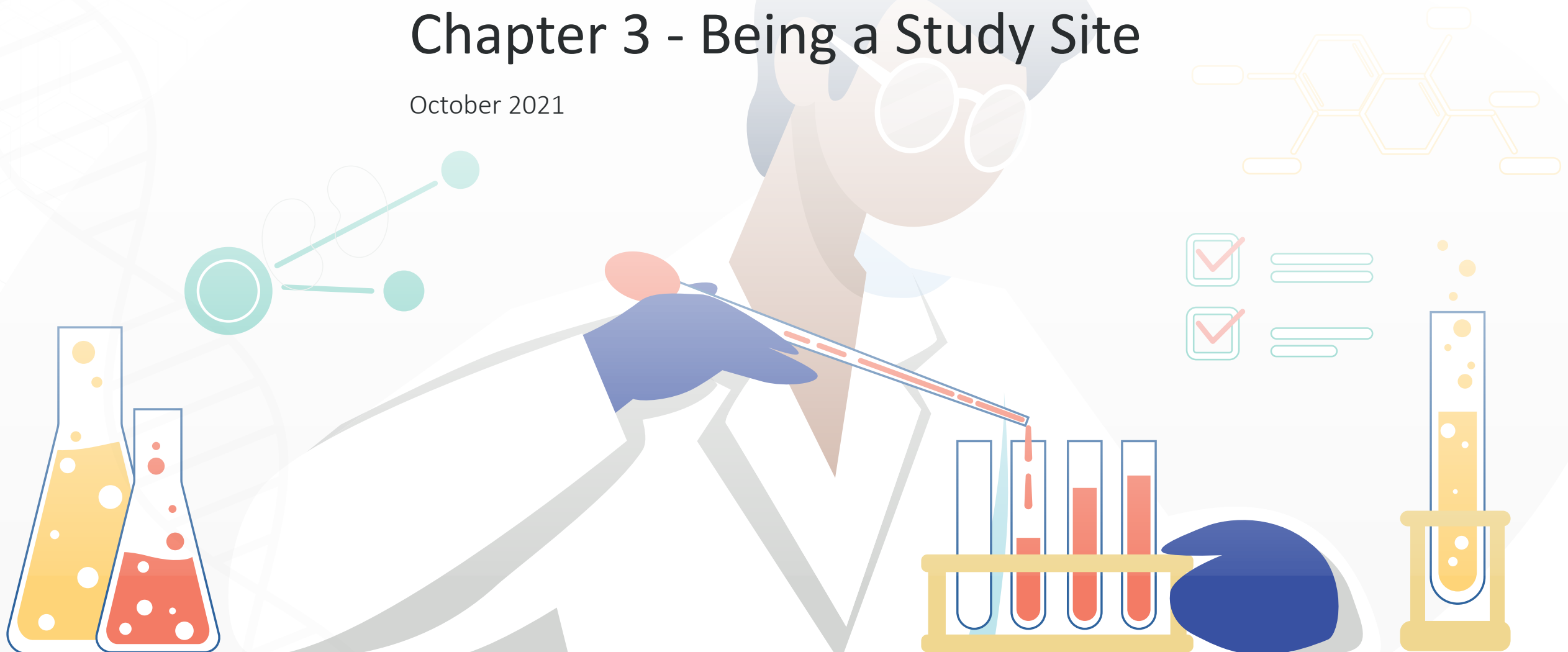
RESEARCH

ACT | CLINICAL TRIALS

CLINICAL TRIALS TOOLKIT

Chapter 3 - Being a Study Site

October 2021



3. BEING A STUDY SITE

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The text below is a transcript of the concepts described in the [ISN-ACT Clinical Trials Toolkit](#). The characters and background story were added to the text to illustrate common research methods used in clinical trials. The names used refer to fictional characters making no reference to actual persons.

3.1 INTRODUCTION¹



Dr. Francisco Aguilar is a young nephrologist from El Salvador, Central America. Alongside neighboring countries, Guatemala, Costa Rica, and Nicaragua, the area has come to international attention for having a high number of cases of “Chronic Kidney Disease of Unknown etiology/Uncertain cause,” also known as CKDu or Mesoamerican nephropathy.

CKDu mainly affects marginalized agricultural communities in specific world regions where many people develop an unexplained, deadly form of kidney disease. Initial surveys conducted in Central America have demonstrated that up to 20-30% of adults in ‘endemic communities’ present a high prevalence of decreased kidney function of unknown origin, possibly of environmental or occupational origin. The most extensively studied CKDu hotspots include Sri Lanka, El Salvador, Nicaragua, Guatemala, and Southern Mexico. Other agricultural regions affected include South India and California’s

Central Valley, where researchers are actively investigating whether resident agricultural workers also demonstrate a decline in kidney function.

Dr. Aguilar had come across cases of CKDu since the beginning of his nephrology practice and was determined to understand the condition better. Most of his patients were males between the ages of 20 and 60 living mainly in rural or agricultural



settings. They had been exposed to extreme working conditions and had experienced a rapid loss of kidney function. Encouraged by colleagues, Dr. Aguilar decided to present his CKDu cases during the [World Congress of Nephrology](#) (WCN), which was selected for a poster presentation.

3.2 POSTER PRESENTATIONS AT THE WCN

At the 2015 World Congress of Nephrology in Cape Town, South Africa, **Dr. Anna Roberts**, a renowned researcher based at the National Institute of Health (NIH), USA, visited the congress poster area before the sessions began. An expert in genomics, she was currently using artificial intelligence to assess factors implicated in the development of kidney diseases. Dr. Roberts always looked for networking opportunities with fellow researchers in the WCN poster area. She was eager to exchange



ideas and get inspired. That day, a study from **Dr. Prisha**, a nephrologist from Sri Lanka, caught her eye. It was a case study discussion describing a whole-exome analysis of two siblings. While one had advanced kidney disease, the other was still

healthy. Adjacent to this study was Dr. Aguilar's description of environmental risk factors associated with the development of CKDu in El Salvador.

After considering both posters, Dr. Roberts realized she could use artificial intelligence to better understand how environmental and genetic factors interact in CKDu's

development. She wanted to design an international clinical study on CKDu using Dr. Francisco Aguilar and Dr. Prisha's data. However, they would have to fulfill the requirements to become a study site in order to participate.

3.3 BECOMING A STUDY SITE²

Both Dr. Aguilar and Dr. Prisha were aware that the skills acquired to become a study site would help them run their own research projects as well as contribute to existing studies. Clinical research is a rewarding part of medicine: While it does take some effort, it potentially provides both clinicians and patients with access to novel tests and treatments. Research leads to a better understanding of disease mechanisms, which helps develop medication to improve patients' lives. It is also a great way to learn about the research process and collaborate with peers. Dr. Roberts proposed a meeting that same day to discuss providing her potential future collaborators with the basic requirements to become a trial site. She wanted to make sure that both doctors understood each step of the process in advance.

3.4 INITIATION STEPS

That evening, in a restaurant with a fantastic view of Table Mountain, Dr. Roberts began by stressing the importance of good communication skills, advising, “Expressing motivation and willingness to join is key.”



«So even if I don’t have all the required elements in place, I can still express my interest in becoming a trial site if I’m confident that others can help me to get my site ready in the meantime?” Dr. Aguilar asked.

“Yes!” Dr. Roberts replied, adding, “After returning to your country, you should nominate one person to become the principal investigator. This person will become the team leader of the investigators. The team might include co-investigators, study coordinators, a pharmacist, and student nurses. For international trials, sufficient English or support from a translator is key to ensure that you understand the protocol and

the electronic case report forms (eCRF) and can communicate effectively with the central study team. The central study team might be researchers and their organization, or a professional study management team (also known as a Contract Research Organization- CRO) hired to coordinate the study.”

Dr. Prisha felt optimistic: She had great leadership and communication skills and felt confident about acting as a team leader. However, she wondered whether she had enough time to lead a clinical trial, knowing that research projects can take up more time than you first think.

Dr. Aguilar was concerned with the need to have access to a local laboratory, radiology, pharmacy services, and basic equipment for handling drugs and laboratory specimens such as a centrifuge and a refrigerator. He would also need access to an appropriate place for patient visits and to store study documentation.



Dr. Roberts outlined some additional important points:

“Once you’ve covered these initial steps, please double-check what elements are already in place and what you’ll need to organize. You will need:

- Sufficient staff, space, and equipment to conduct the study.
- Access to a specific patient population at your institution or contacts with other institutions to refer patients.
- An appropriate license for all procedures outlined in the study protocol.
- Access to an accredited Institutional Review Board (IRB) or Independent Ethics Committee (IEC).

You should also make sure that:

- The head of your institution will sign the study agreement.
- You monitor and report on any Adverse Events (AEs) and Serious Adverse Events (SAEs).
- You will be able to follow the screening and recruitment schedule and study protocol procedures.
- You will be able to provide further medical care to study participants or refer them elsewhere.

3.5 CONCLUSION

Dr. Roberts returned to the hotel full of enthusiasm at the idea of collaborating on a research project with Dr. Aguilar and Dr. Prisha. Equally, Dr. Aguilar and Dr. Prisha were thrilled that presenting an abstract at WCN had led to participating in an international study that had the potential to impact their careers and their communities positively. They both looked forward to the chance to connect to the global research community and contribute to advancing innovation in nephrology.

A year later, the ISN i3C – the [International Consortium of Collaborators in CKDu](#), a collaborative group focused on building capacity, lifting the standard of investigative research, and advocating for research and clinical care in CKDu – hosted a series of multidisciplinary meetings and research-in-progress webinars to provide real-time feedback to ongoing investigations and provide two sets of guidelines on screening and researching CKDu.



The ISN also hosts the ISN Observatory of CKDu, [an observatory of ongoing CKDu studies](#)—to which more than 50 groups have contributed data—so that young, motivated scientists and physicians like Dr. Prisha and Dr. Aguilar can find like-minded collaborators, and ultimately, help improve the health of people in the affected communities.

Don't miss the next chapter in February 2022!

Notes

- 1 <https://www.theisn.org/initiatives/what-is-ckdu/>
- 2 <https://www.theisn.org/in-action/research/clinical-trials-isn-act/isn-act-toolkit/being-a-trial-site/>

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Design and layout: International Society of Nephrology

Editing and proofreading: International Society of Nephrology