

# CLINICAL TRIALS TOOLKIT

## Chapter 6 - Trial publication and reporting

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# 6. TRIAL PUBLICATION AND REPORTING

By M.D. Ph.D. Augusto Cesar Soares dos Santos Junior (Brazil) and M.D. Brendan Smyth (Australia).

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.

## 6.1 IMPROVING PRE-DIALYSIS CARE



Dr. Luciana Garcia is an active and committed member of the [ISN Young Nephrologists Committee](#).

Based in Lima, Peru, she leads a program to improve pre-dialysis care.

The transition from pre-dialysis care to kidney replacement therapy (KRT)

presents significant challenges in Dr. Garcia's region. In general, late-stage chronic kidney disease (CKD) outcomes are suboptimal because of late referrals to nephrologists, fragmentation of care, inadequate patient education, low adherence to protocols, and poor communication.

In Lima, the importance of dialysis modality planning, definitive vascular access, and elective initiation KRT are frequently underestimated, so urgent medical attention is usually required. Limited resources prevent Dr. Garcia from implementing all facets of her care plan simultaneously.

Dr. Garcia conducted a controlled clinical trial to demonstrate the benefits of a structured, staggered implementation of KRT within a pre-dialysis care program. She wants to publish the findings after a planned follow-up period.

## 6.2 THE ART OF SCIENTIFIC WRITING

Scientific publications are one of the most important tools for communicating discoveries to the scientific community and the general public. But physicians and other healthcare professionals often lack the skills needed to write scientific papers.

The ISN regularly organizes regional courses presented by experts in scientific writing. These courses are designed to equip doctors



and researchers from a range of backgrounds with the writing skills required to get their research work published.

### 6.2.1 The Main Structure

Dr. Garcia was excited when she was selected to join a recent [ISN Scientific Writing Course](#). Her mentor, Dr. Joachim Csaba, a Hungarian nephrologist based in Budapest, trained at the



MacMaster University in Canada, where he gained experience in evidence-based medicine. Dr. Csaba is a renowned scientist in his homeland, with several publications in major scientific journals. He is keen to pass on his expertise to future generations.

The newly-designed online version of the course meant they could schedule their sessions together when convenient. After meeting his new mentee, Dr. Csaba began:

“Scientific writing follows a specific structure comprising an abstract, introduction, methods, results and references.”

“Authors can learn to make their text more readable. For instance, the introduction should contextualize the main question, outline the importance of investigating the topic, and address how the main question will be answered. This can usually be done in two

or three short paragraphs – long introductions often make the text difficult to understand and can discourage even an interested reader.”

Dr. Garcia was pleased with the hands-on advice she was receiving. Reporting and publication were the final steps in her research project, and she wanted readers to notice her paper. As she continued taking notes, Dr. Csaba highlighted some other important concepts:



“When writing your results, make sure you state your principal findings clearly. In the discussion, remember to address the strengths and weaknesses of the study, and don’t forget to compare your findings with those of previous studies. Make a clear and concise conclusion and try to connect your study with possible future research.”

### 6.2.2 Analysis and reporting

On the second day of the course, Dr. Csaba introduced another essential topic:

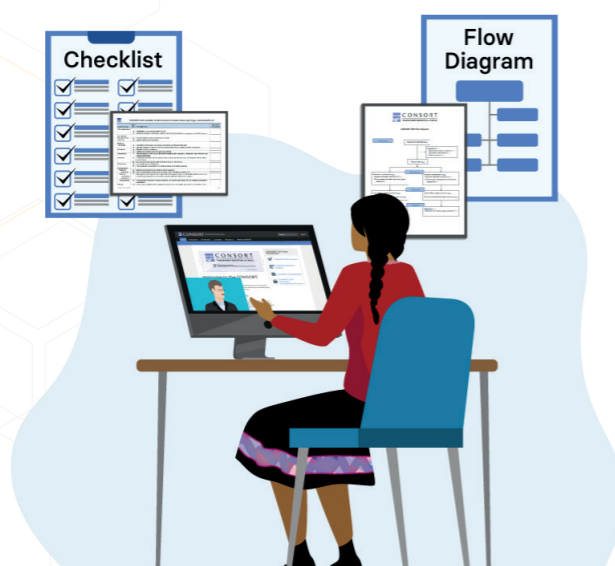
“Most biomedical journals require authors to comply with certain guidelines for reporting clinical trials. These guidelines present

standard statements on reporting research methodology and findings, often as checklists or flow diagrams.”

Dr. Luciana Garcia asked if she could record Dr. Csaba’s instructions. She wanted to be able to refer back to them when writing up her results. Agreeing, Dr. Csaba continued:

“The «[CONSORT Statement](#)» is an evidence-based set of recommendations for reporting randomized trials endorsed by most biomedical journals. It offers a standard way for authors to prepare reports of trial findings, facilitates complete and transparent reporting, and aids critical appraisal and interpretation. This helps improve the quality and reporting of the different types of research used to make healthcare decisions.

Containing a 25-item checklist and flow diagram freely available for viewing and downloading [online](#), it is one of the most used statements for reporting clinical trial results.



Extensions to the «CONSORT Statement» give additional guidance for randomized control trials with specific designs, data or interventions.”

Dr. Csaba added:

“The «[WHO Statement on Public Disclosure of Clinical Trial Results](#)» recommends that the Trial ID or registry identifier code/number be included in all publications of clinical trials and as part of the abstract when submitted to [PubMed](#) and other bibliographic search databases for easy linking of trial reports with clinical trial registry site records.”

With all this new information in mind, Dr. Garcia asked Dr. Csaba how much time she would have to submit her findings once the trial was completed.



He replied:

“The main findings of clinical trials must be submitted for publication in a peer-reviewed journal within 12 months of study completion and should preferably be published through an open-access platform or otherwise made publicly available within 24 months of study completion.”

To round off the second day of the ISN Scientific Writing Course, Dr. Csaba concluded:

“Analysis and reporting are more than just formatting your results into a scientific paper. Targeting your work to the right audience is an essential step that can boost the impact of your study.”

Dr. Garcia had really enjoyed the course. She was passionate about improving pre-dialysis care. Now, with the support of Dr. Csaba, she was confident that she would succeed in publishing her findings.



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