

[Survey intro page]

Thank you for your interest in taking the survey.

Before we begin, we would like to answer some questions you might have about the survey.

What is the purpose of ICH Good Clinical Practice (GCP)¹?

The introduction to ICH GCP states:

“Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.”

“This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.”

“This guideline should be read in conjunction with other ICH guidelines relevant to the conduct of clinical trials (e.g., E2A (clinical safety data management), E3 (clinical study reporting), E7 (geriatric populations), E8 (general considerations for clinical trials), E9 (statistical principles), and E11 (pediatric populations)).”

—Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2), page 1

The ICH GCP Guideline provides a unified standard for the European Union, Japan, the United States, Canada, Switzerland, Brazil, Republic of Korea, Singapore, China and Chinese Taipei.

Is ICH E6(R2) under renovation?

Yes. The *ICH Reflection on the ongoing “GCP Renovation”*: Modernization of ICH E8 and the Subsequent Renovation of ICH E6² describes a potential approach to renovate the ICH E8 and E6 Guidelines.

The approach includes:

1. Renovation/augmentation of the current *ICH E8 General Considerations for Clinical Trials* on principles of study design and planning for an appropriate level of data quality,

and

¹https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf

² ICH Reflection on “GCP Renovation”: Modernization of ICH E8 and Subsequent Renovation of ICH E6, January 2017, <https://bit.ly/2TMtrGs>

2. Renovation of *ICH E6 Good Clinical Practices* to address a broader range of study types and data sources, together with guidance on good clinical investigative site practices.

The E8(R1) draft guideline³ was released for public comment in May 2019. At the time of survey development, ICH GCP (E6) renovation has not been initiated.

What is the purpose of this survey?

The Clinical Trials Transformation Initiative (CTTI) is gathering evidence on the use of ICH GCP among stakeholders affected by ICH GCP. The purpose of this survey is to:

1. Provide an opportunity for stakeholders to identify areas in ICH GCP that are—and are not—in need of renovation.
2. For CTTI to identify stakeholders for follow-up telephone interviews to learn more about their experiences in using ICH GCP and their suggestions for ICH GCP renovation.

Who is CTTI and why are they conducting this survey?

The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, that seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials (<https://www.ctti-clinicaltrials.org>).

CTTI independently developed the survey and will independently analyze the data from the survey and follow-up interviews. ICH is not conducting this survey and interviews, and CTTI is not conducting this survey and interviews at the request of ICH.

What will be done with the survey and interview findings?

CTTI will provide the findings to ICH for their consideration prior to the renovation of ICH GCP. CTTI has no agreement with ICH that they will use the information in the planned ICH GCP renovation. It is recognized the findings only represents feedback from those stakeholders with whom CTTI has made contact.

CTTI will also post the raw survey dataset on the CTTI website (<https://www.ctti-clinicaltrials.org/>) for others to analyze if they wish.

How long will the survey take?

The survey will take about 10 to 15 minutes to complete.

Who should take the survey?

Individuals who are currently engaged or have been involved in clinical research and reference ICH GCP in the conduct of research should complete the survey.

Should the survey be completed individually or in group?

Individuals should complete the survey on their own. The survey is not designed for groups to combine their answers and respond.

How do I know if I was selected for a follow-up telephone interview?

You will have an opportunity at the end of the survey to add your name and contact information if you would like to participate in a follow-up interview. CTTI will contact you if you were selected for an interview.

³ https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E8/E8-1E1WG_Step2_DraftGuideline_2019_0508.pdf

Who do I contact if I want to know more about the survey and interview, or have questions?

If you have questions about this study, please contact Annemarie Forrest, RN, MS, MPH, CTTI's Director of Projects at annemarie.forrest@duke.edu.

Let's get started—we look forward to learning from you!

Section 1: Demographics

This section asks questions about you and your role in research.

1. **In what country or countries do you currently or have ever conducted research or been involved in research? Check all that apply.** (Drop down menu of all countries, organized by region, including a response at the top of the list, "I have never conducted or been involved in any research" If the latter is chosen, end survey.)
2. **In what country is your primary place of employment? Check only one country.** (Drop down menu of all countries, organized by region.)
3. **What type of organization best describes your place of employment? Choose only one.**
 - University/academic research center affiliated with a hospital/medical center
 - University/academic research center *not* affiliated hospital/medical center
 - Hospital/medical center *not* affiliated with a university/academic research center
 - Pharmaceutical company or biotechnology company
 - Contract research organization (commercial/for profit)
 - Governmental organization that regulates medical products
 - Governmental organization that does not regulate medical products
 - Private research site
 - Non-governmental organization or not-for-profit organization
 - Trade/professional organization
 - Private foundation
 - Patient advocacy group
 - Not affiliated with a specific organization
 - Prefer not to respond
4. **Which of the following best describes your main role in research? Choose only one.**
 - Principal investigator, co-investigator, sub-investigator, site investigator
 - Clinical research associate/research coordinator/study nurse
 - Medical provider (healthcare provider who delivers medical care to study participants)
 - Clinical operations personnel
 - Ethics review/Institutional Review Board personnel
 - Regulatory affairs personnel
 - Government regulator
 - Monitor
 - Inspector
 - Quality assurance/quality control personnel
 - Data manager
 - Data collector
 - Data analyst
 - Pharmacist
 - Laboratory personnel
 - Patient advocate
 - Prefer not to respond

5. **How long have you been involved in research?**

- 1 year or less
- 2 to 5 years
- 6 to 10 years
- 11 to 20 years
- More than 20 years
- Prefer not to respond

6. **Which of the following *best describes* the type of research are currently or have been involved in? Check all that apply. See definitions below.**

a. **Clinical Research**

- Diagnostic studies**
 - Phase I, II, or III clinical research on medicinal products (drugs, vaccines, and biologicals)
 - Phase IV: Post-marketing/post-approval clinical research on medicinal products
 - Observational clinical research
 - Other clinical research on medicinal products
 - Other clinical research not on medicinal products
 - I do not conduct clinical research
 - Prefer not to respond

b. **Non-Clinical Research**

- Epidemiological research
- Social science and behavioral research
- I do not conduct non-clinical research
- Prefer not to respond

Diagnostic research: Investigators who assess better ways to identify a particular disorder or condition.

Observational clinical research: “Investigators assess health outcomes in groups of participants...Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial).” (www.clinicaltrials.gov)

Epidemiological research: Investigators assess “all the factors that determine the presence or absence of diseases and disorders. Epidemiological studies [assess] how many people have a disease or disorder, if those numbers are changing, and how the disorder affects our society and our economy.” (<https://www.nidcd.nih.gov/health/statistics/what-epidemiology>)

Social science and behavioral research: Investigators assess “the complex interplay between biological, behavioral, social, and environmental processes, including phenomena that occur both within the organism (e.g., genetics, neurobiology, emotion, perception, cognition) and external to the organism (e.g., environment, social relationships, societal factors, culture, policy).” (<https://obsr.od.nih.gov/about/bssr-definition>)

[If type of research was selected] Please answer the following questions based on your involvement in diagnostic studies.

- **Does this research produce evidence for regulatory decision making?**
 - Yes
 - No
 - I do not know

- **Is the study team expected to follow ICH GCP?**
 - Yes
 - No
 - I do not know
 - Prefer not to respond

- **Why is the study team expected to follow ICH GCP? Check all that apply.**
 - Regulation mandate
 - Institutional requirement
 - Funder or sponsor requirement
 - No other guidance to follow
 - None of the reasons stated above
 - I do not know
 - Prefer not to respond

[If type of research was selected] Please answer the following questions based on your involvement in Phase I, II, or III clinical research on medicinal products (drugs, vaccines, and biologicals).

- **Does this research produce evidence for regulatory decision making?**
 - Yes
 - No
 - I do not know

- **Is the study team expected to follow ICH GCP?**
 - Yes
 - No
 - I do not know
 - Prefer not to respond

- **Why is the study team expected to follow ICH GCP? Check all that apply.**
 - Regulation mandate
 - Institutional requirement
 - Funder or sponsor requirement
 - No other guidance to follow
 - None of the reasons stated above
 - I do not know
 - Prefer not to respond

[If type of research was selected] Please answer the following questions based on your involvement in Phase IV: Post-marketing/post-approval clinical research on medicinal products.

- **Does this research produce evidence for regulatory decision making?**
 - Yes
 - No
 - I do not know

- **Is the study team expected to follow ICH GCP?**
 - Yes
 - No
 - I do not know
 - Prefer not to respond

- **Why is the study team expected to follow ICH GCP? Check all that apply.**
 - Regulation mandate
 - Institutional requirement
 - Funder or sponsor requirement
 - No other guidance to follow
 - None of the reasons stated above
 - I do not know
 - Prefer not to respond

[If type of research was selected] Please answer the following questions based on your involvement in observational clinical research.

- **Does this research produce evidence for regulatory decision making?**
 - Yes
 - No
 - I do not know

- **Is the study team expected to follow ICH GCP?**
 - Yes
 - No
 - I do not know
 - Prefer not to respond

- **Why is the study team expected to follow ICH GCP? Check all that apply.**
 - Regulation mandate
 - Institutional requirement
 - Funder or sponsor requirement
 - No other guidance to follow
 - None of the reasons stated above
 - I do not know
 - Prefer not to respond

[If type of research was selected] Please answer the following questions based on your involvement in other clinical research on medicinal products.

- **Does this research produce evidence for regulatory decision making?**
 - Yes
 - No
 - I do not know

- **Is the study team expected to follow ICH GCP?**
 - Yes
 - No
 - I do not know
 - Prefer not to respond

- **Why is the study team expected to follow ICH GCP? Check all that apply.**
 - Regulation mandate
 - Institutional requirement
 - Funder or sponsor requirement
 - No other guidance to follow
 - None of the reasons stated above
 - I do not know
 - Prefer not to respond

[If type of research was selected] Please answer the following questions based on your involvement in other clinical research not on medicinal products.

- **Does this research produce evidence for regulatory decision making?**
 - Yes
 - No
 - I do not know

- **Is the study team expected to follow ICH GCP?**
 - Yes
 - No
 - I do not know
 - Prefer not to respond

- **Why is the study team expected to follow ICH GCP? Check all that apply.**
 - Regulation mandate
 - Institutional requirement
 - Funder or sponsor requirement
 - No other guidance to follow
 - None of the reasons stated above
 - I do not know
 - Prefer not to respond

[If type of research was selected] Please answer the following questions based on your involvement in **epidemiological research.**

- **Does this research produce evidence for regulatory decision making?**
 - Yes
 - No
 - I do not know

- **Is the study team expected to follow ICH GCP?**
 - Yes
 - No
 - I do not know
 - Prefer not to respond

- **Why is the study team expected to follow ICH GCP? Check all that apply.**
 - Regulation mandate
 - Institutional requirement
 - Funder or sponsor requirement
 - No other guidance to follow
 - None of the reasons stated above
 - I do not know
 - Prefer not to respond

[If type of research was selected] Please answer the following questions based on your involvement in **social science and behavioral research.**

- **Does this research produce evidence for regulatory decision making?**
 - Yes
 - No
 - I do not know

- **Is the study team expected to follow ICH GCP?**
 - Yes
 - No
 - I do not know
 - Prefer not to respond

- **Why is the study team expected to follow ICH GCP? Check all that apply.**
 - Regulation mandate
 - Institutional requirement
 - Funder or sponsor requirement
 - No other guidance to follow
 - None of the reasons stated above
 - I do not know
 - Prefer not to respond

7. Are you currently using or have you ever used mobile applications, such as smart phones and smart watches, or other wearables, ingestibles, implantables, or mobile technologies containing sensors, for the *remote capture of efficacy or safety outcomes data* for regulatory decision making?
- Yes
 - No
 - I do not know
 - Prefer not to respond
8. Are you currently using or have you ever used routine health care data (e.g., hospital data, registries, national clinical datasets, medical records, administrative data) for *capture of efficacy or safety outcomes data* for regulatory decision making?
- Yes
 - No
 - I do not know
 - Prefer not to respond
9. Have you received training on ICH GCP?
- Yes
 - No
 - I do not know
 - Prefer not to respond
10. How often do you rely on ICH GCP to do your research role?
- Never
 - Rarely
 - Occasionally
 - Regularly
 - Prefer not to respond

Thank you. You will now be asked questions about the sections of ICH GCP.

Section 2: Review of the ICH GCP General Principles

Listed below are the [13 ICH GCP Principles](#).

For each principle, please indicate whether you believe the information provided in the ICH GCP E6 guidance document needs to be revised or does not need to be revised. You can also choose “no comment.”

ICH GCP Principles	Response		
	Revision is needed	Revision is NOT needed	No comment
1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).			
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.			
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.			
4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.			
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.			
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.			
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.			
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).			

<p>9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.</p>			
<p>10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. ADDENDUM This principle applies to all records referenced in this guideline, irrespective of the type of media used.</p>			
<p>11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).</p>			
<p>12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.</p>			
<p>13. Systems with procedures that assure the quality of every aspect of the trial should be implemented. ADDENDUM Aspects of the trial that are essential to ensure human subject protection and reliability of trial results should be the focus of such systems.</p>			

Section 3: Review of the Sections of ICH GCP

Listed below are the topics described in each section of [ICH GCP](#).

For each topic, please indicate whether you believe the information provided for that topic needs to be revised or does not need to be revised. You can also choose “no comment.”

Statement by Section of ICH GCP	Response		
	Revision is needed	Revision is NOT needed	No comment
IRB/IEC			
Responsibilities			
Composition, Functions and Operations			
Procedures			
Records			
Investigator			
Investigator's Qualifications and Agreements			
Adequate Resources			
Medical Care of Trial Subjects			
Communication with IRB/IEC			
Compliance with Protocol			
Investigational Product(s)			
Randomization Procedures and Unblinding			
Informed Consent of Trial Subjects			
Records and Reports			
Progress Reports			
Safety Reporting			
Premature Termination or Suspension of a Trial			
Final Report(s) by Investigator			
Sponsor			
Quality Management			
Quality Assurance and Quality Control			
Contract Research Organization (CRO)			
Medical Expertise			
Trial Design			
Trial Management, Data Handling, and Record Keeping			
Investigator Selection			
Allocation of Responsibilities			
Compensation to Subjects and Investigators			
Financing			
Notification/Submission to Regulatory Authority(ies)			
Confirmation of Review by IRB/IEC			
Information on Investigational Product(s)			

Statement by Section of ICH GCP	Response		
	Revision is needed	Revision is NOT needed	No comment
Manufacturing, Packaging, Labelling, and Coding Investigational Product(s)			
Supplying and Handling Investigational Product(s)			
Record Access			
Safety Information			
Adverse Drug Reaction Reporting			
Monitoring			
Audit			
Noncompliance			
Premature Termination or Suspension of a Trial			
Clinical Trial/Study Reports			
Multicentre Trials			
Clinical Trial Protocol and Protocol Amendments			
General Information			
Background Information			
Trial Objectives and Purpose			
Trial Design			
Selection and Withdrawal of Subjects			
Treatment of Subjects			
Assessment of Efficacy			
Assessment of Safety Statistics			
Direct Access to Source Data/Documents			
Quality Control and Quality Assurance			
Ethics			
Data Handling and Record Keeping			
Financing and Insurance			
Publication Policy			
Supplements			
Investigator's Brochure			
General Considerations			
Contents of the Investigator's Brochure			
Essential Documents			
Collecting of essential documents does not reflect investigator competency.			
Before the Clinical Phase of the Trial Commences			
During the Clinical Conduct of the Trial			
After Completion or Termination of the Trial			

Section 4: Follow up Interviews

We are interested in conducting 1 hour, telephone interviews with stakeholders who want to share their experiences with using ICH GCP.

We want to learn about situations where ICH GCP has worked well. We also want to learn about situations where ICH GCP has not worked well and how it can be improved to provide better guidance for those situations. We want to talk with individuals from different regions of the world.

We will share these experiences with ICH, together with your name and organization.

Are you interested in taking part in a follow-up, 1 hour telephone interview?

Yes → Please enter your name and email address so that we can contact you

Name:

Email address:

Please note that your name will be linked with the information you entered in the survey.

No

Section 5: Additional Comments

CTTI is also providing an opportunity for stakeholders to provide very specific recommended changes to the ICH GCP E6 document. This includes recommendations for wording changes. They will provide all recommended changes—directly as they are provided by each stakeholder—to ICH.

CTTI will send information about this opportunity at a later date.

Thank you for your time and interest!