



Welcome

INTRODUCTION TO GCP GUIDELINES
ENSURING QUALITY IN CLINICAL RESEARCH

2022

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GRANDHI RAVEENA
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INDEX

- DEFINITION
- ROLES AND RESPONSIBILITIES
- ESSENTIAL DOCUMENTS OF GCP
- ELEMENTS OF GCP
- PRINCIPLES OF GCP
- ICH GUIDELINES TOPICS
- CONCLUSION/IMPORTANCE OF GCP
- REFERENCES



Introduction to GCP Guidelines

DEFINITION:

GCP is a standard for the design, conduct, performance, monitoring, auditing, recording, analyzing, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the right, integrity, and confidentiality of trial subjects are protected.

GCP guidelines: ensuring quality in clinical research

GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human patients



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GCP guidelines include standards on how clinical trials should be conducted, provide assurance of the safety of the newly developed compounds, and focuses on the protection of human rights in clinical trials

It defines roles and responsibilities of:

- IRB(institutional review boards): To safe guard the rights, safety, and well being of all trials subjects. This done by initial, continuing and annual review process. It should review all documents given to participants. Maintenance of records should be ensured.
- Clinical research invigilators: should be familiar with investigation products and their use, obtain informed consent from subjects. Interact with patients and research team, show up to date documents to IRB
- Clinical trial sponsors: trail management, data handling, record keeping, and independent data monitoring committee which contain qualified personnels to supervise overall conduct of the study. They assesses the progress of the clinical trials, maintain SOPS for electronic data processing.
- Monitors (CRA's): provide assistance to investigators ensuring that the trials is conducted as documented properly, Helps in coordinate meetings and information sharing

Essential documents in GCP

- Study protocol with all amendments
- Signed consent form for all subjects
- IRB submission forms/approval memos
- All versions of a consent form
- Samples of recruitment advertisements
- For all investigational drug studies; an investigational brochure



Elements of GCP

- IRB/IEC –institutional review board /institutional ethics committee
- Investigator
- Sponsor
- Clinical trial protocol and protocol amendment
- Investigators brochure

Principles of ICH GCP

- Conduct trials according to GCP guidelines
- Weigh risks vs benefits: trials should be initiated and continued only if anticipated benefits justify risks
- Protect the subjects in view of their rights, safety, well-being
- Have adequate information to justify a trial: the information may be clinical and nonclinical on an investigational product



Principles of ICH GCP

- Write a sound protocol which should be clear and detailed
- Receive IRB/IEC approval: should be conducted in compliance with the protocol
- Use qualified physicians: to ensure patient safety and ethics
- Use qualified supporting staff, in terms of their education, training, experience



Principles of ICH GCP

- Obtain informed consent: from the subject prior to clinical trials
- Record information appropriately, maintain the confidentiality of the records
- Protect the confidentiality of the subject, respecting their privacy in accordance with the applicable regulatory requirements
- Handle, manufacture, and store the investigational product appropriately as per GMP in accordance with the protocol

Principles of ICH GCP

- Implement quality systems; in every aspect of the trial
- May have more regulations that apply locally
- Do not conflict with national regulations which is Schedule Y of the Drugs and cosmetic act 1940: national regulations are for the import, manufacturing, marketing, and approval of new drugs in India



Principles of ICH GCP

- Follow SOP's (standard operating procedures) detailed instructions:

Describing what, when, where, and by whom of performing an activity.

*SOPs are detailed written instructions to achieve uniformity in the performance of a specific function.



Purpose

- To harmonize the regulations and guidelines for the drug development
- To remove duplication in the development of the review process
- The GCP guidelines are applicable for drugs, biologics, medical devices
- They are approved by ICH members
- They are adopted by National regulatory authorities

ICH GUIDELINES TOPICS



It contains 4 topics

- Quality topics: which relate to chemicals and pharmaceutical quality assurance
 - eg: Q1 stability testing
- Safety topics: relate to preclinical studies
 - eg: S1 Carcinogenic testing
- Efficacy topics: relate to clinical studies in human subjects
 - eg: E6 GCP
- Multidisciplinary topics: cross-cutting topics
 - eg: additional issues that intersect with the main pro

CONCLUSION

Importance of ICH GCP guidelines

- Protection of clinical trial subjects
- Avoiding unethical practices
- Same across the whole world
- Ensure quality of care
- Data accuracy and reliability
- Prevention of alteration of data
- Aimed at improving the clinical development process and many more



REFERENCES

- <http://www.fda.gov/oc/gcp/guidelines.htm>
- <http://www.clinicaltrials.gov>
- <http://en.Wikipedia.org/wiki/ICH-GCP>
- Handbook: good laboratory practice(GLP), WHO library catalogue-in-publications data,2nd edition,7,15-20.
- <https://www.pharmdguru.com>

Thank You!

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Definitions

- A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
- Good clinical practice is a set of internationally recognized ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible

Purpose of GCP

To harmonize the regulations and guidelines for the drug development.

Participants

Regulatory agencies/
Industry
representatives from
Europe, Japan and
US

Goal

- To remove redundancy / duplication in development of the review process
- For new medical product, the data should demonstrate:
 - Safety
 - Quality
 - Efficacy

Process

- The developed guidelines were applicable for:
 - Drugs
 - Biologics
 - Medical devices
- Approved by ICH members
- Adopted by the National Regulatory Authorities

1948	Nurenburg Code
1961	Thalidomide (excl USA)
1962	USA – The Drugs Amendment Act – Established the IND procedure
1964	Worldwide – The Declaration of Helsinki (for protection of the trial subjects)
1968	UK – The Medicines Act (for the control of clinical trials and product marketing)
1976	Germany – The Drug Law
1978	USA – The FDA GCP Established
1986	UK – The ABPI Guidelines Issued

1989	Nordic – GCP Guidelines Established
1991	France - decree giving Bonnes Pratiques Cliniques legal force
1991	European Community EC GCP Guidelines Operational
1991	Australian GCP
1993	WHO GCP Guidelines
1997	The ICH Guidelines on GCP Operational
2000	Worldwide – The DoH (declaration of Helsinki) Amended
2005	EU – “The GCP Directive”
2005	WHO – Handbook for GCP Guidance for implementation

Nurenbuerg Code

- Required is the voluntary, well-informed, understanding consent of the human subject in a full legal capacity.
- The experiment should aim at positive results for society that cannot be procured in some other way.
- It should be based on previous knowledge (like, an expectation derived from animal experiments) that justifies the experiment.
- The experiment should be set up in a way that avoids unnecessary physical and mental suffering and injuries.
- It should not be conducted when there is any reason to believe that it implies a risk of death or disabling injury.
- The risks of the experiment should be in proportion to (that is, not exceed) the expected humanitarian benefits.

- The risks of the experiment should be in proportion to (that is, not exceed) the expected humanitarian benefits.
- Preparations and facilities must be provided that adequately protect the subjects against the experiment's risks.
- The staff who conduct or take part in the experiment must be fully trained and scientifically qualified.
- The human subjects must be free to immediately quit the experiment at any point when they feel physically or mentally unable to go on.
- Likewise, the medical staff must stop the experiment at any point when they observe that continuation would be dangerous.

Declaration of Helsinki

- Research must conform to scientific principles
- Protocol and independent ethics committees
- Supervision and conduct of trial by suitably qualified persons
- Objectives and possible benefits balanced against risk to subjects
- Privacy respected and minimal physical and impact on the subject
- Informed consent

Good Clinical Practice (GCP)

- An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human beings, Public assurance that the rights, safety, and well being of trial subjects are protected
- Results in credible data
- Consistent with the Declaration of Helsinki

Thirteen Principles of GCP

- Clinical trials should be conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki, that are consistent with GCP and the applicable regulatory requirements.
- Before the trial is initiated , foreseeable risks and inconveniences should be weighed against the anticipated benefits for the individual trial subjects and society. The trial should be initiated and continued only if the anticipated benefits justify the risks.
- The rights, safety and well – being of the trial subjects are the most important considerations and should prevail over the interest for science and society.
- The available clinical and non – clinical information on an investigational product should be adequate to support the proposed clinical trial.
- Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

- The trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB) / independent ethics committee (IEC) approval / favorable opinion.
- The medical care given to and medical decisions made on behalf of, subjects should always be the responsibility of the qualified physician or, when appropriate, a qualified dentist.
- Each individual involved in conducting the trials should be qualified by education, training and experience to perform his/her respective tasks.
- Freely given informed consent should be obtained from every subject prior to the clinical trial participation.
- All clinical trial information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

- The confidentiality of the records that could identify the trial subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements
- Investigational products should be manufactured, handled and stored in accordance with the applicable good manufacturing practices (GMP). They should be used in accordance with the approved protocol.
- Systems with procedures that assure the quality of every aspect of the trial should be implemented.

GCP =
Quality data +
Ethics

Thank you



GOOD CLINICAL PRACTICE

- An Overview



Dr.D.VARUN
Professor & Academic Director
SRI INDU INSTITUTE OF PHARMACY
Hyderabad



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INTERNATIONAL
CLINICAL TRAIL
DAY
JAMES LIND
FATHER OF CLINICAL
RESEARCH

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Topics for Discussion

1

What is GCP

2

GCP Guidelines

3

Core Principles of GCP Guidance

4

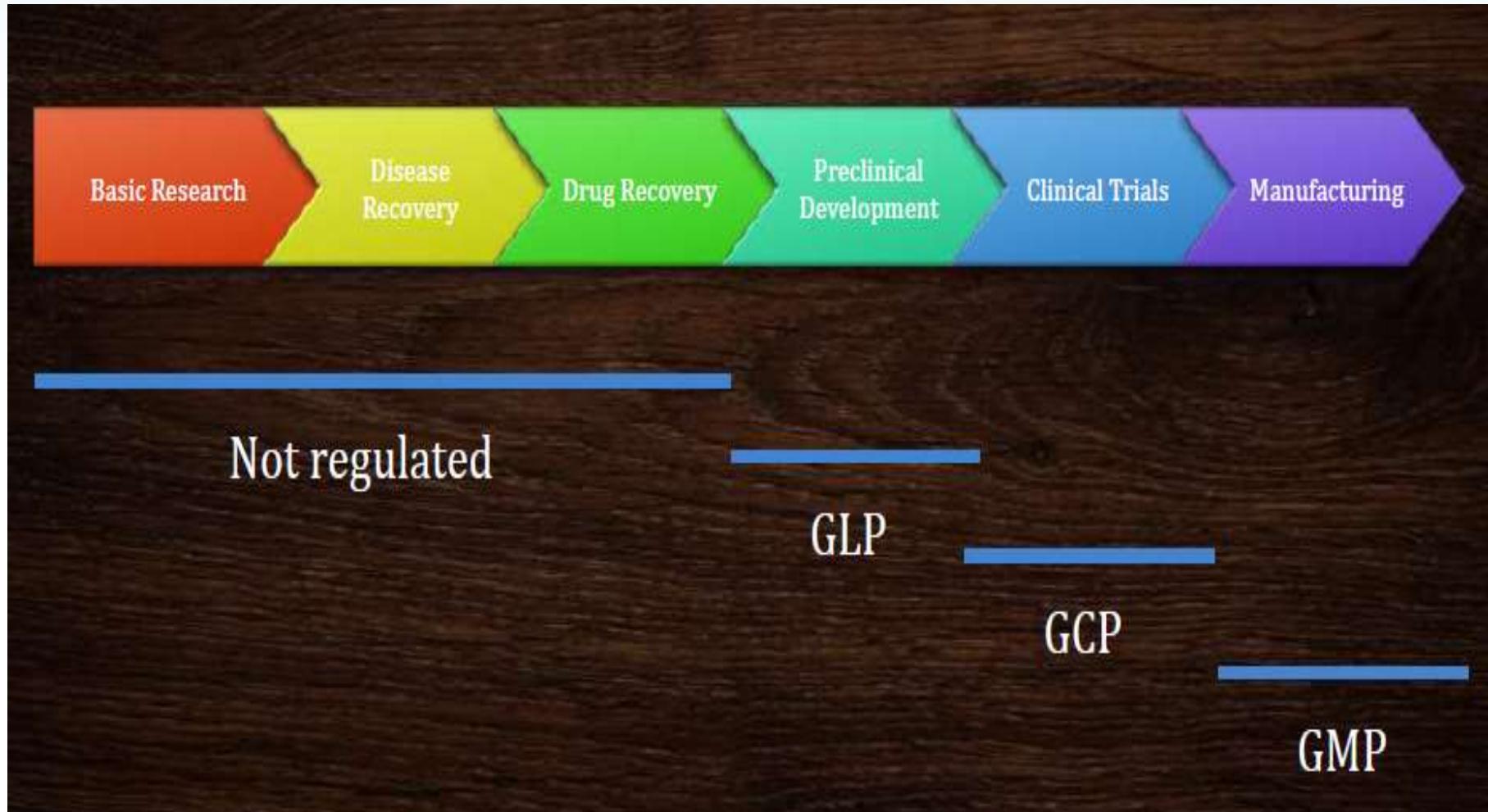
Historical Perspective of Human Research Conducts

5

Clinical Trials, Stages, Benefits, Risks, IRB, Reporting



RESEARCH REGULATORY





GCP ????

- Good Clinical Practice (GCP) is defined as a ‘standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected’

GCP Guidelines



- ✓ Mainly focused on the protection of human rights in clinical trial.
- ✓ To provide assurance of the safety of the newly developed compounds.
- ✓ To provide standards on how clinical trials should be conducted.
- ✓ To define the roles and responsibilities of clinical sponsors, clinical research investigators, Clinical Research Associates, and monitors.



GCP Guidelines...continued

- ❑ GCPs are in general internationally accepted best practices for conducting clinical trials and device studies.
- ❑ They are defined as an international ethical and scientific standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.
- ❑ Compliance with GCPs provide public assurance that the rights and safety of participants in human subject research are protected and that the data that arises from the study is credible.



Thirteen Core Principles of GCP Guidance

1. Clinical trials should be conducted in accordance with the ethical principles that are consistent with GCP and the applicable regulatory requirements.
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 non clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial .

Thirteen Core Principles of GCP Guidance...continued

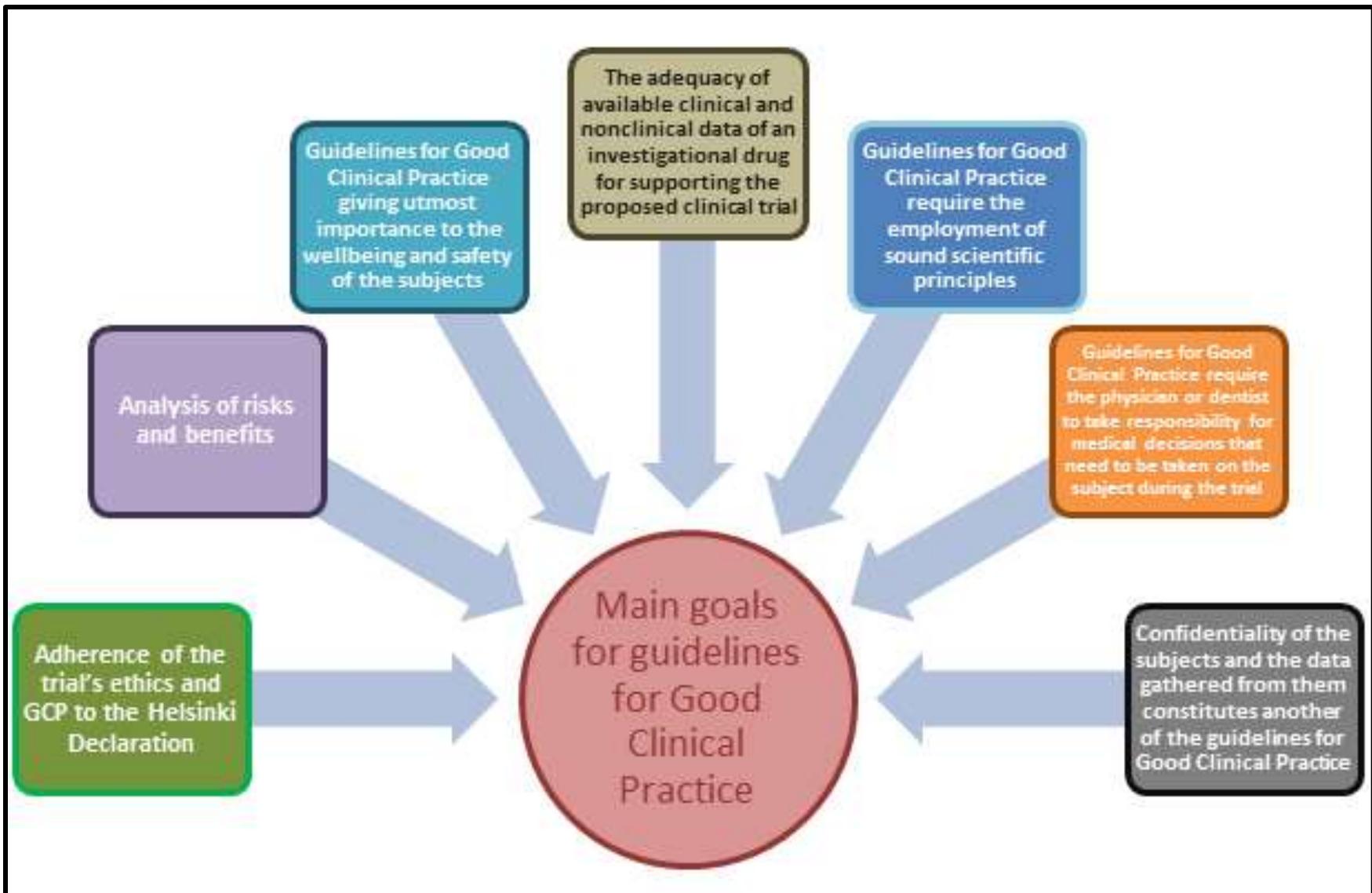


5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior **Institutional Review Board (IRB)/Independent Ethics Committee (IEC)** approval/favorable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be with **responsibility**.
8. Each individual involved in conducting a trial should be **qualified by education, training, and experience** to perform his or her respective tasks .
9. **Voluntarily given informed consent** should be obtained from every subject prior to clinical trial participation .

Thirteen Core Principles of GCP Guidance...continued



10. All **clinical trial information** should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.
11. The **confidentiality of records** that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements.
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.
13. Systems with procedures that **assure the quality** of every aspect of the trial should be implemented.





(US) Historical Perspective of Human Research Conducts

1. Nuremberg Code, **1946**

2. Kefauver Amendments, **1962** - Thalidomide

3. Declaration of Helsinki, **1964**

4. National Research Act, **1974** - Tuskegee Syphilis Study (**1932-1972**)

5. Belmont Report, **1979**



Nazi Medical War Crimes During World War II

- Experiments conducted by Nazi physicians during World War II were unprecedented in their scope and the degree of harm and suffering to which human beings were subjected.
- Typically, the experiments resulted in death, disfigurement or permanent disability, and as such are considered as examples of medical torture.
- "Medical experiments" were performed on thousands of concentration camp prisoners and included deadly studies and tortures such as-
 - ✓ Injecting people with gasoline and live viruses.
 - ✓ Immersing people in ice water.
 - ✓ Forcing people to ingest poisons.

**Incisions made by medical personnel
that were purposely infected with
bacteria, dirt, and slivers of glass.**





Victim of a tuberculosis medical Experiment.



Prisoner in a Compression Chamber

An experiment to determine altitudes at which aircraft crews could survive without oxygen



Immersing People in Ice Water

- With the intent of discovering means to prevent and treat Hypothermia.
- 280 to 300 victims
- One study forced subjects to endure a tank of ice water for up to five hours.



■ December 9, 1946 - American Military Tribunal opened criminal proceedings against 23 leading German Physicians and administrators for crimes against humanity - **16 found guilty**.

■ German Physicians conducted medical experiments on thousands of camp prisoners **without their consent**.

■ Most of the participants of these experiments died or were permanently crippled.

■ This led to development of Nuremberg Code of Medical Ethics.



NUREMBERG CODE



- The Nuremberg Code was established in 1948, stating that “ The voluntary consent of the human participant is absolutely essential ”.
- It did not carry the force of law, but the Nuremberg Code was the first International document which advocated voluntary participation and informed consent.

KEFAUVER AMENDMENTS



- 1960s - Thalidomide as sedative in pregnancy used in Europe (but not approved by US FDA).
- Deformities in fetus.
- No informed consent (not approved by FDA).
- 1962 US Senate hearings Kefauver Amendments passed into law - For the first time, drug manufacturers were required to prove to the FDA the effectiveness of their products before marketing them.





TUSKEGEE SYPHILIS STUDY

- Study on 600 low income African-American by U.S. Public Health Service.
- Free medical examination – but not told of diagnosis.
- Many died of syphilis.
- Stopped in 1973 by the U.S. Department of Health, Education, and Welfare.
- 1974 National Research Act passed – National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research established.
- The commission produce Belmont Report (1979).



BELMONT REPORT

- Three basic ethical principals

1. Autonomy/respect for persons (Individuals should be treated as autonomous agents & Persons with diminished autonomy are entitled to protection).

2. Beneficence (Human participants should not be harmed & Research should maximize possible benefits and minimize possible risks) and

3. Justice (benefits and risks of research must be distributed fairly)

which are the cornerstone for regulations involving human participants.



DECLARATION OF HELSINKI

World Medical Association - recommendations guiding medical doctors in biomedical research involving human participants

1. Research with humans should be based on the results from laboratory and animal experimentation.
2. Research protocols should be reviewed by an independent committee prior to initiation.
3. Informed consent from research participants is necessary.
4. Research should be conducted by medically/scientifically qualified individuals.
5. Risks should not exceed benefits.

Revised - 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008, 2013

SEVEN ETHICAL PILLARS OF CLINICAL RESEARCH

(HELSINKI Declaration)



- Autonomy
- Beneficence
- Non- Malfeasance
- Fidelity
- Truthfulness
- Confidentiality
- Justice

AUTONOMY



Consent

Para 20 - The subjects must be volunteers and informed participants in the research project.

Para 22 - freely-given informed consent, preferably in writing

-

BENEFICENCE



Para 5 well-being of the human subject should take precedence over the interests of science and society



NON- MALFEASANCE

Para 16 - Preceded by careful assessment of predictable risks and burdens

Attempt to avoid any act or treatment plan that would harm the patient



FIDELITY – Duty of Care

Para 11 - Medical research involving human subjects must be based on generally accepted scientific principles, thorough knowledge of the scientific literature and on adequate laboratory and, where appropriate, animal experimentation.

Para 15 - Conducted only by clinically competent medical person.



TRUTHFULNESS - Honesty

Para 27 - Both authors & investigators are obliged to preserve the accuracy of the results.

Negative as well as positive results **should** be published



CONFIDENTIALITY

Para 21- Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information.

JUSTICE



Para 30 - Every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

Para 9 - Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human Subjects.

Para 17 - Physicians should cease any investigation if the risks outweigh the potential benefits.



DECLARATION OF HELSINKI – BASIC PRINCIPLES

1. Confirm to accepted scientific principles.
2. Design formulated in experimental protocol, reviewed by IEC.
3. Conducted by qualified and trained persons.
4. Importance in proportion to inherent risk.
5. Assessment of risks vs. benefits.
6. Safeguard subject's integrity (privacy).
7. Abstain unless hazards are predictable.
8. Preserve accuracy when publishing.
9. Adequately inform or right to withdraw.
10. Obtain true informed consent in writing.
11. Reliance on legal guardian.
12. State compliance with Declaration.

ICH GUIDELINES ON GCP



- ✓ Clinical Safety E1 – E2F
- ✓ Clinical Study Reports E3
- ✓ Dose-Response Studies E4
- ✓ Ethnic Factors E5
- ✓ Good Clinical Practice E6
- ✓ Clinical Trials E7 – E11
- ✓ Guidelines for Clinical Evaluation by Therapeutic Category E12
- ✓ Clinical Evaluation E14
- ✓ Pharmacogenomics E15 – E16
- ✓ Joint Safety/Efficacy Topic M3



Section Break











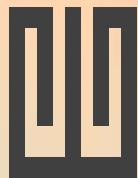












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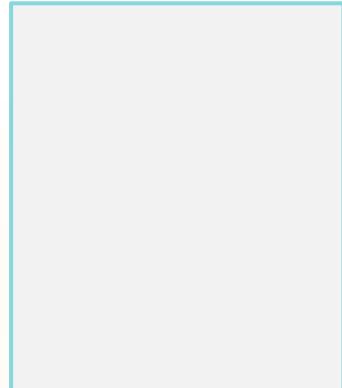
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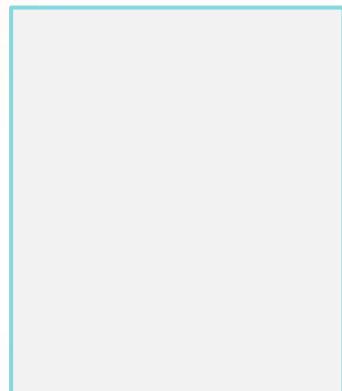
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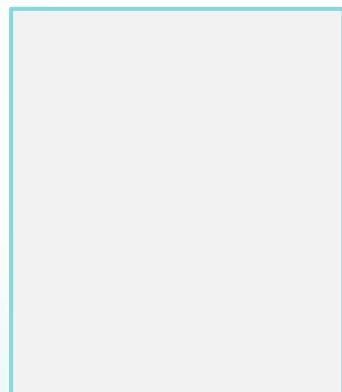
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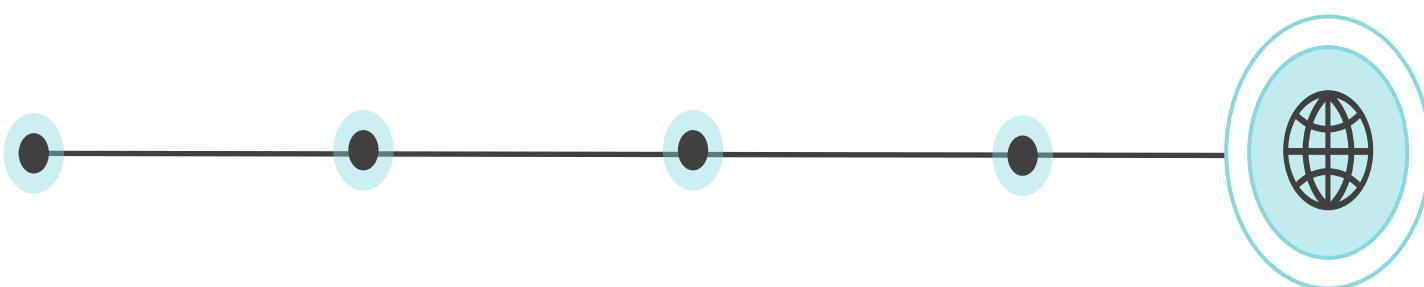
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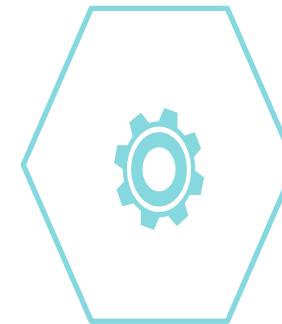
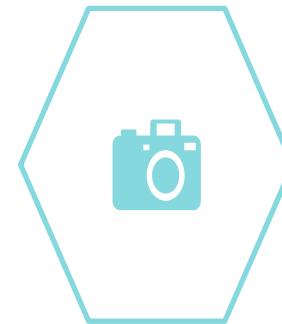
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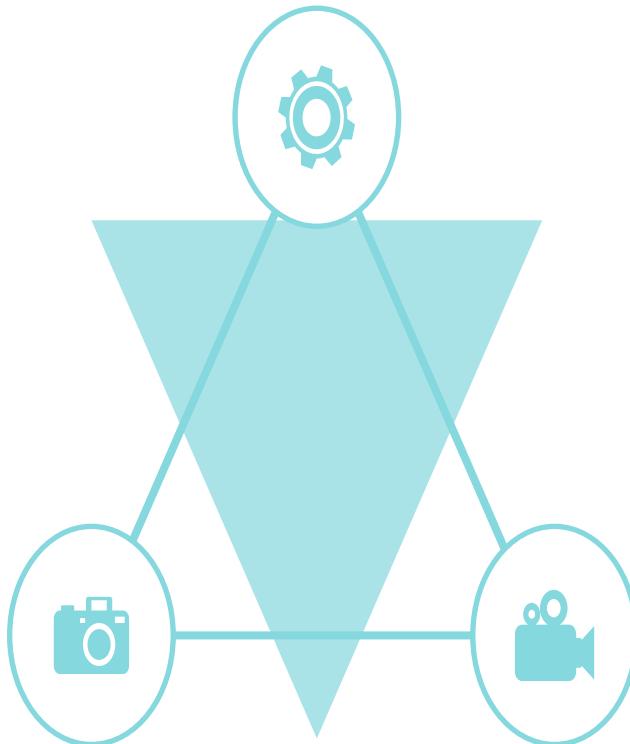
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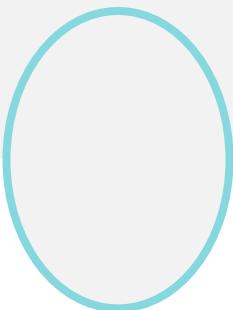
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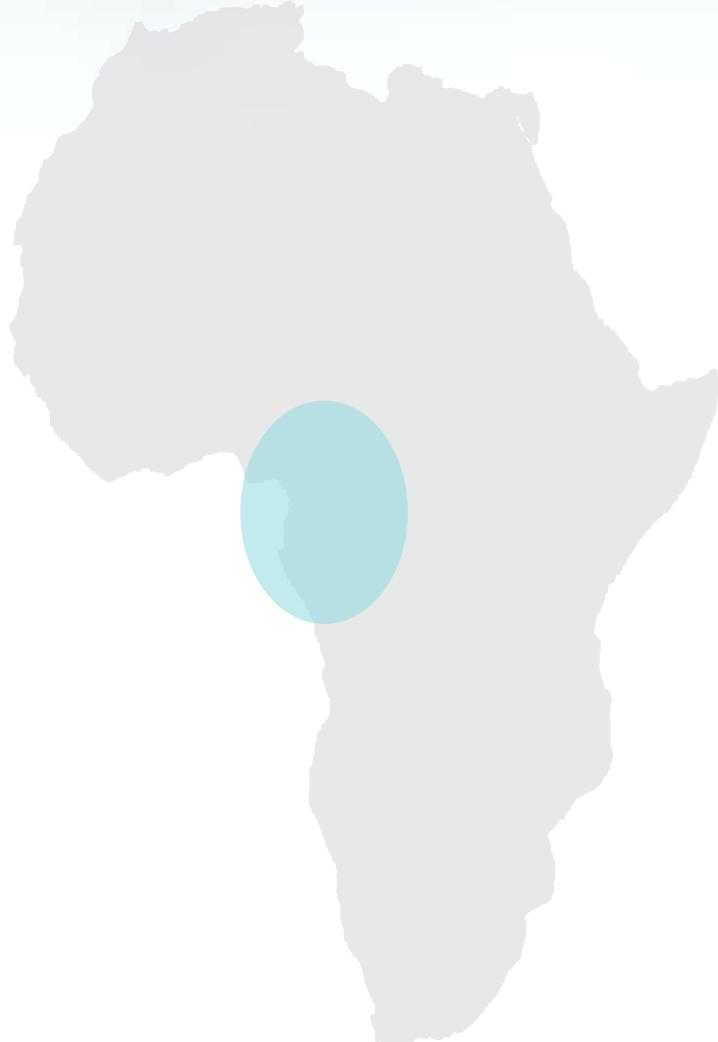
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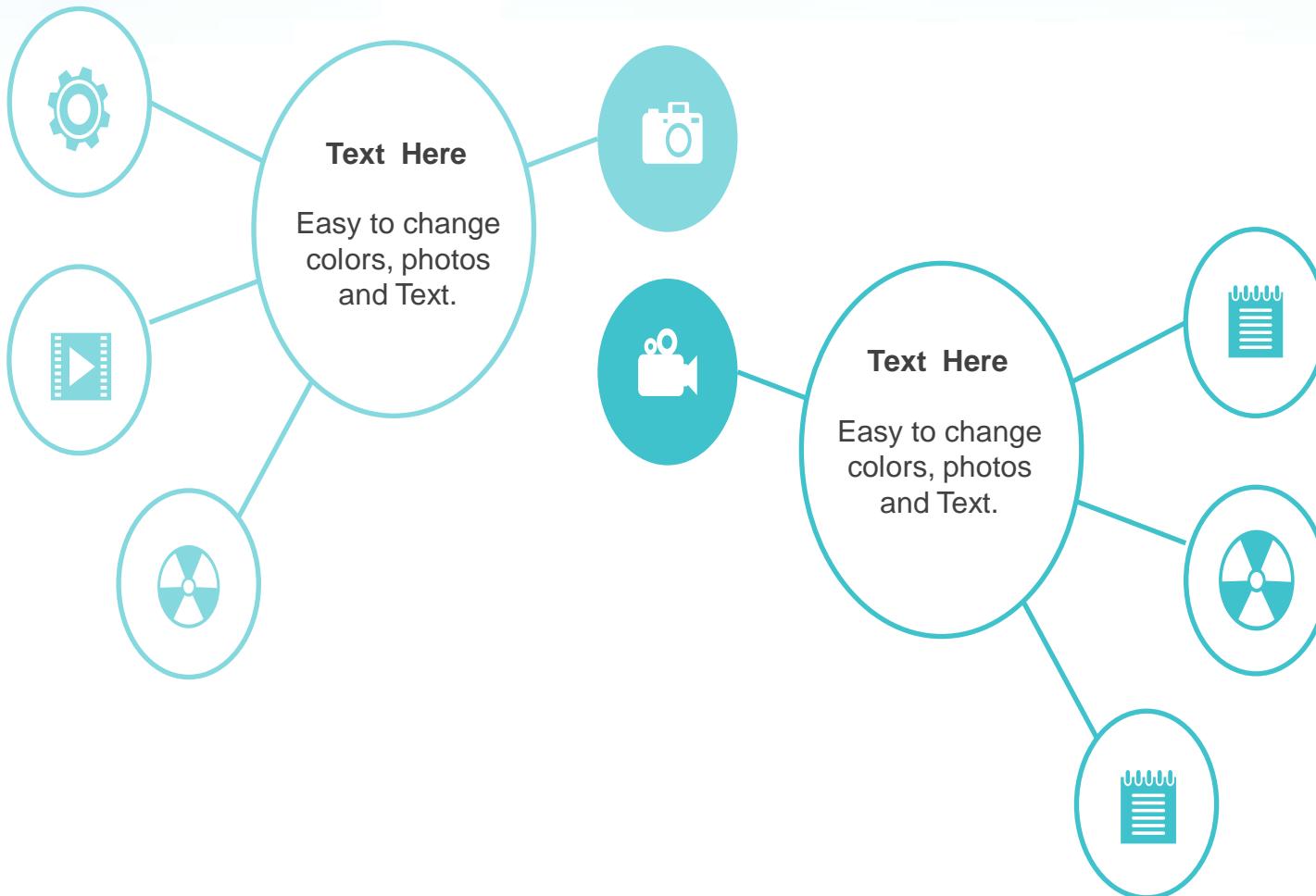
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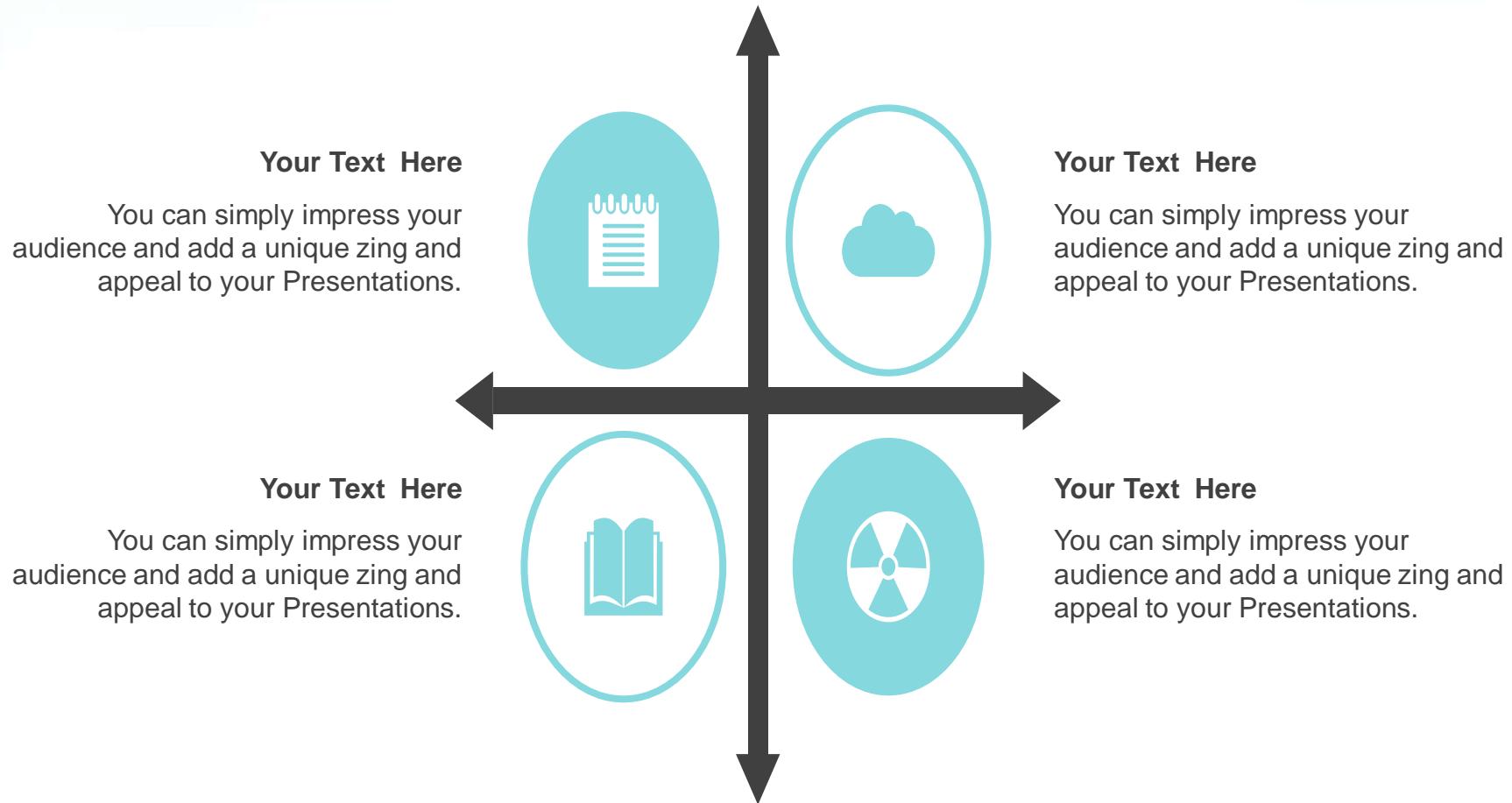
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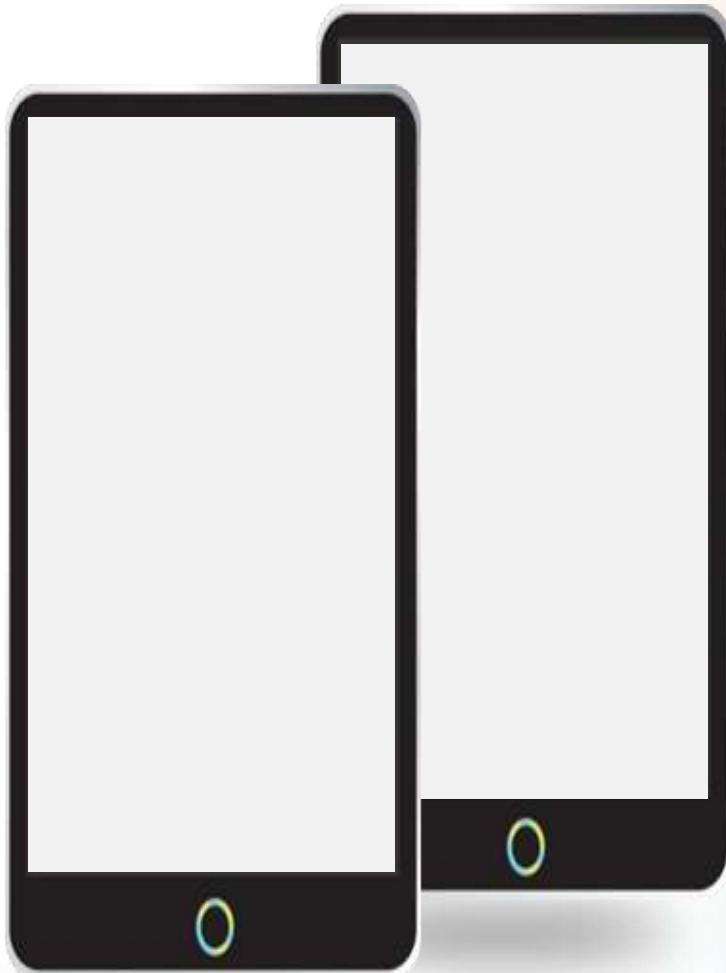
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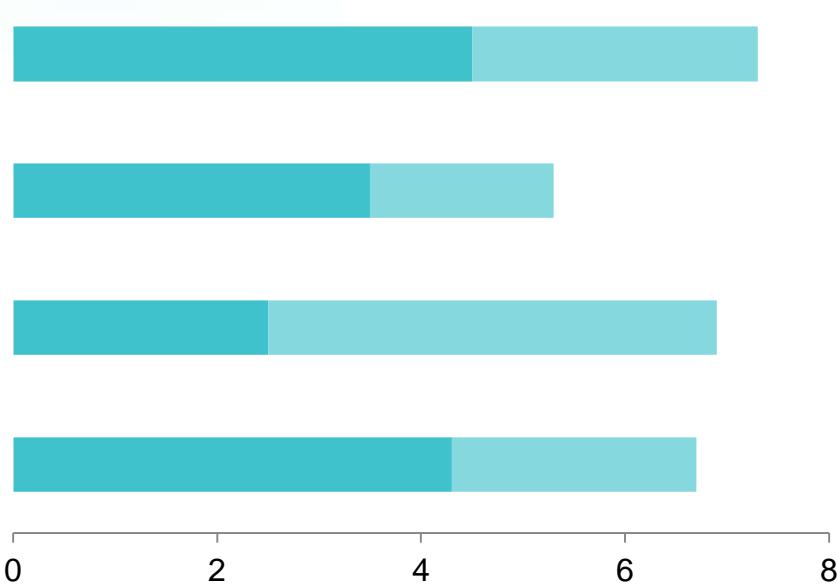


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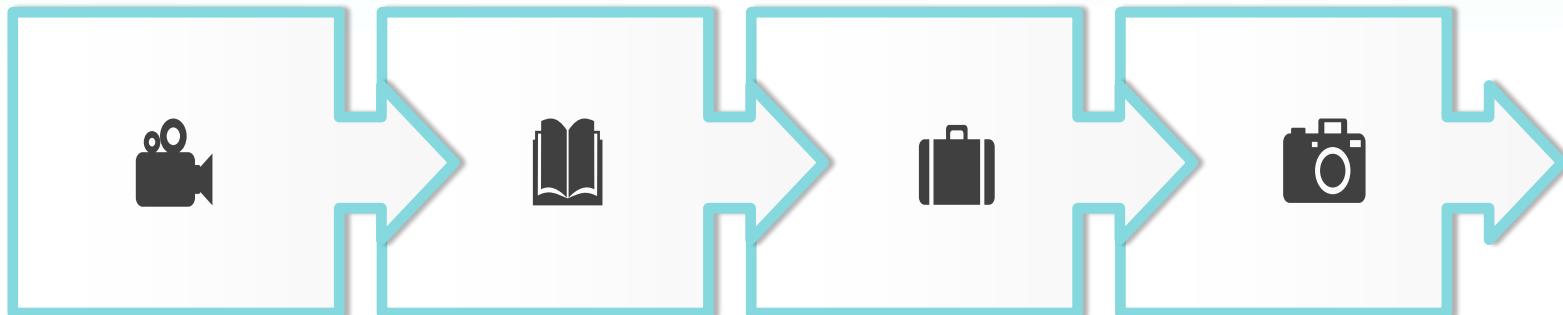


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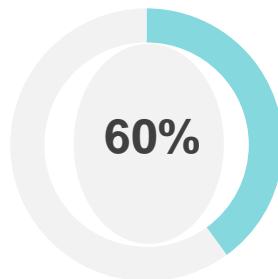
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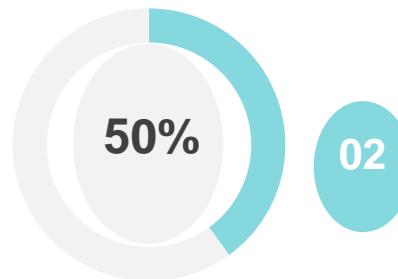
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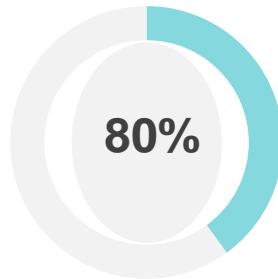
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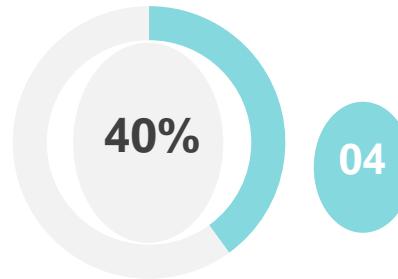


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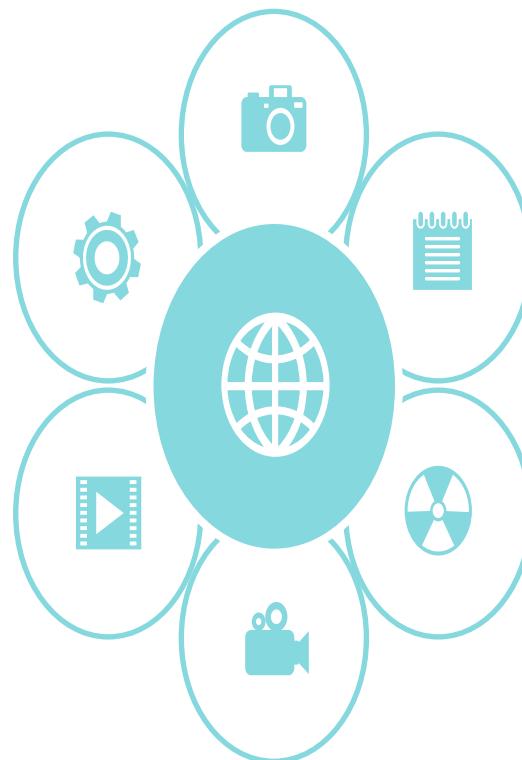


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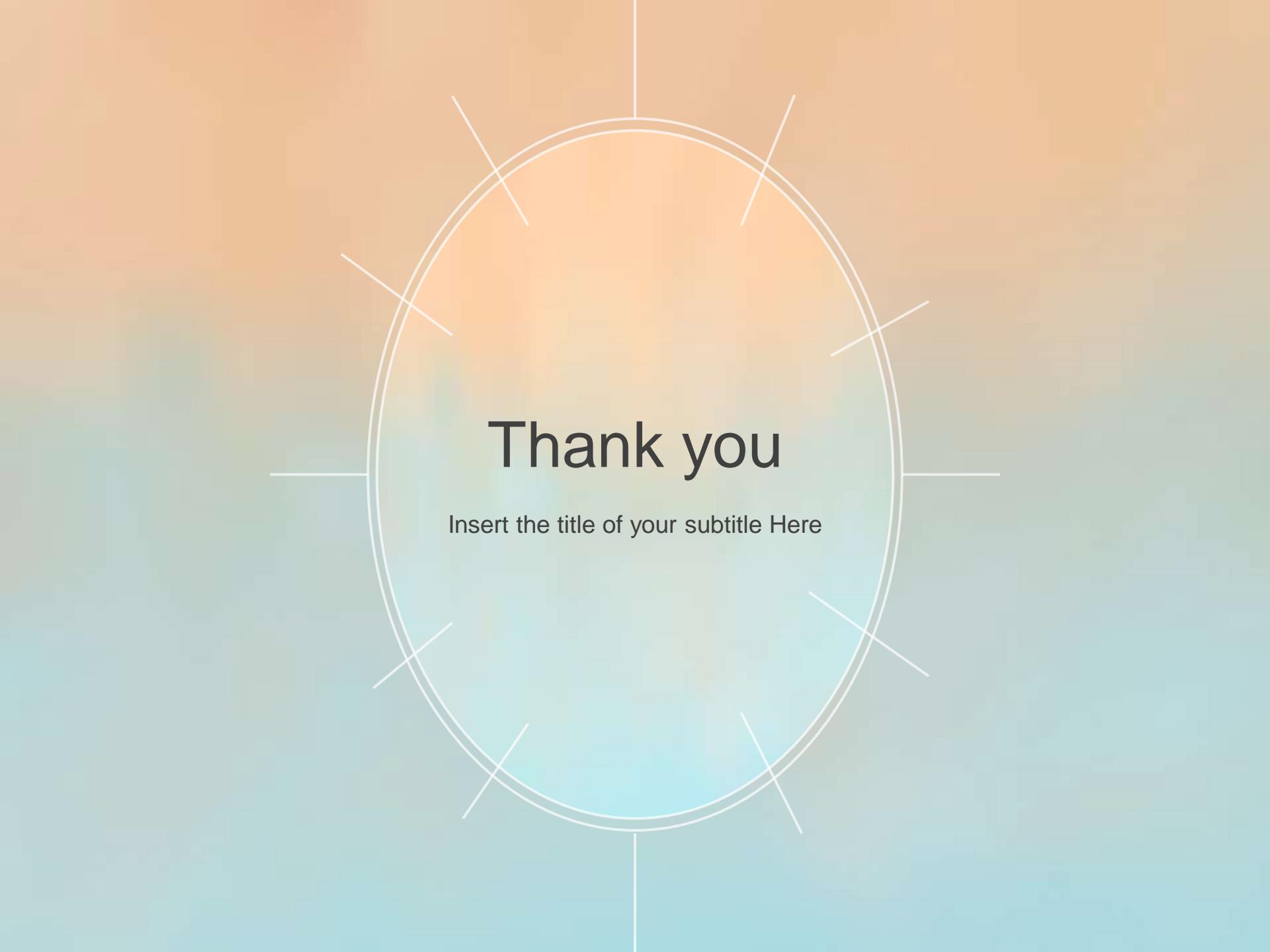
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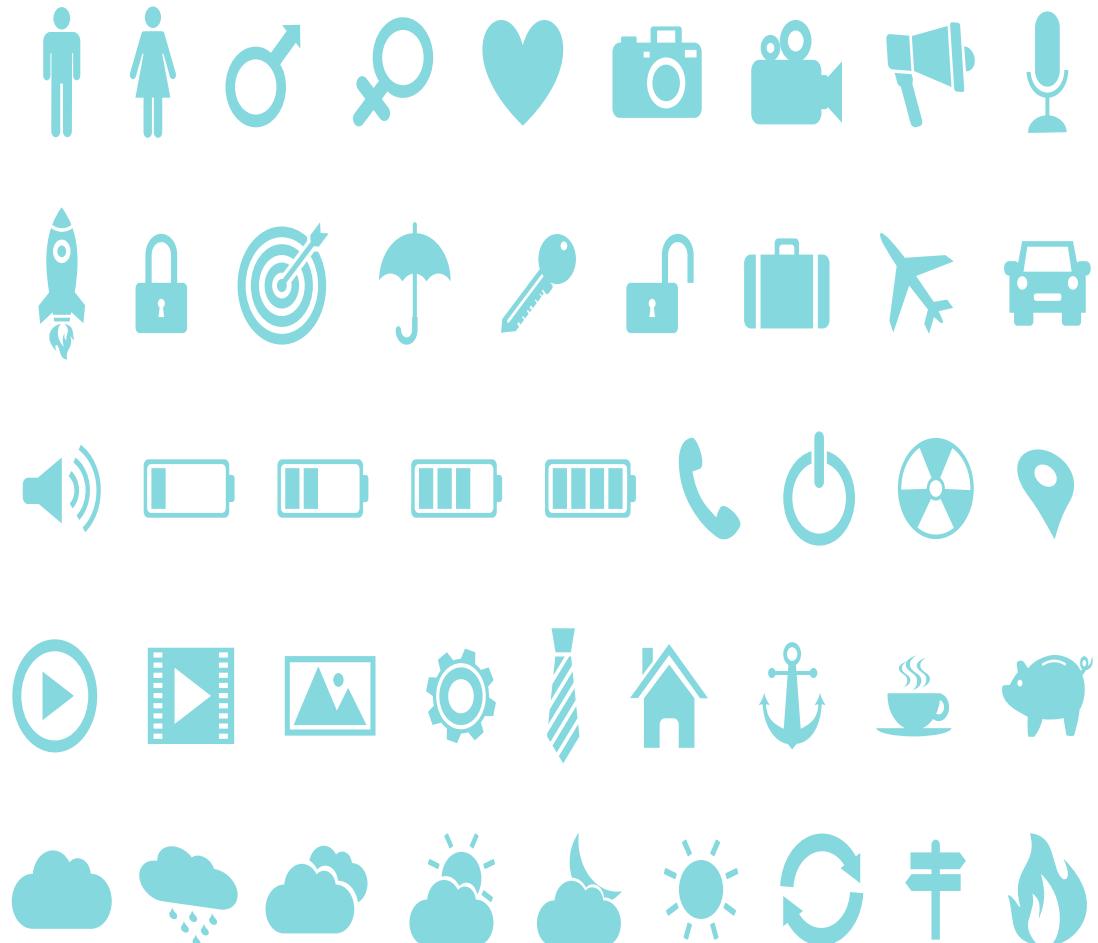
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