GOOD CLINICAL PRACTICE

- An Overview

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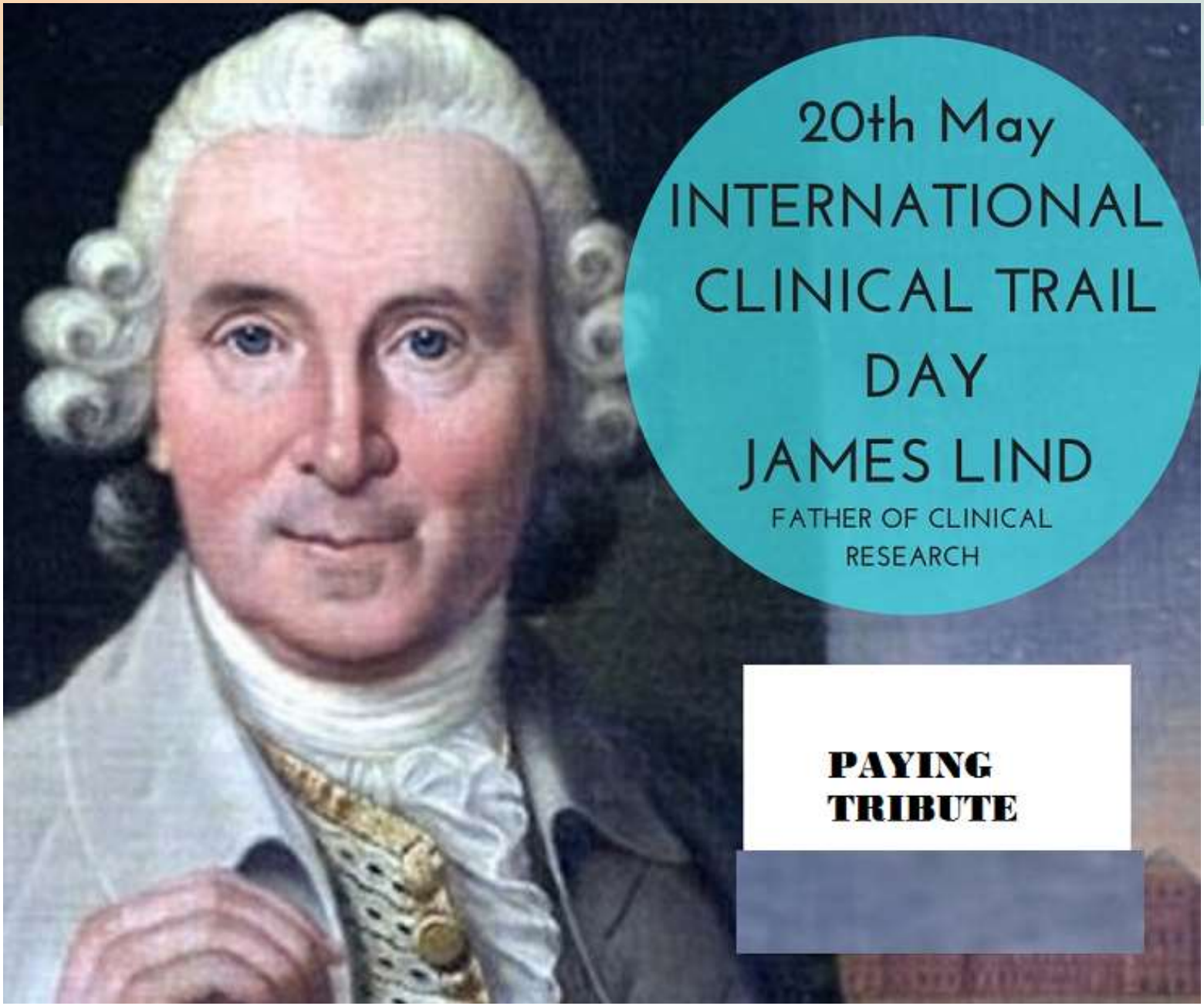
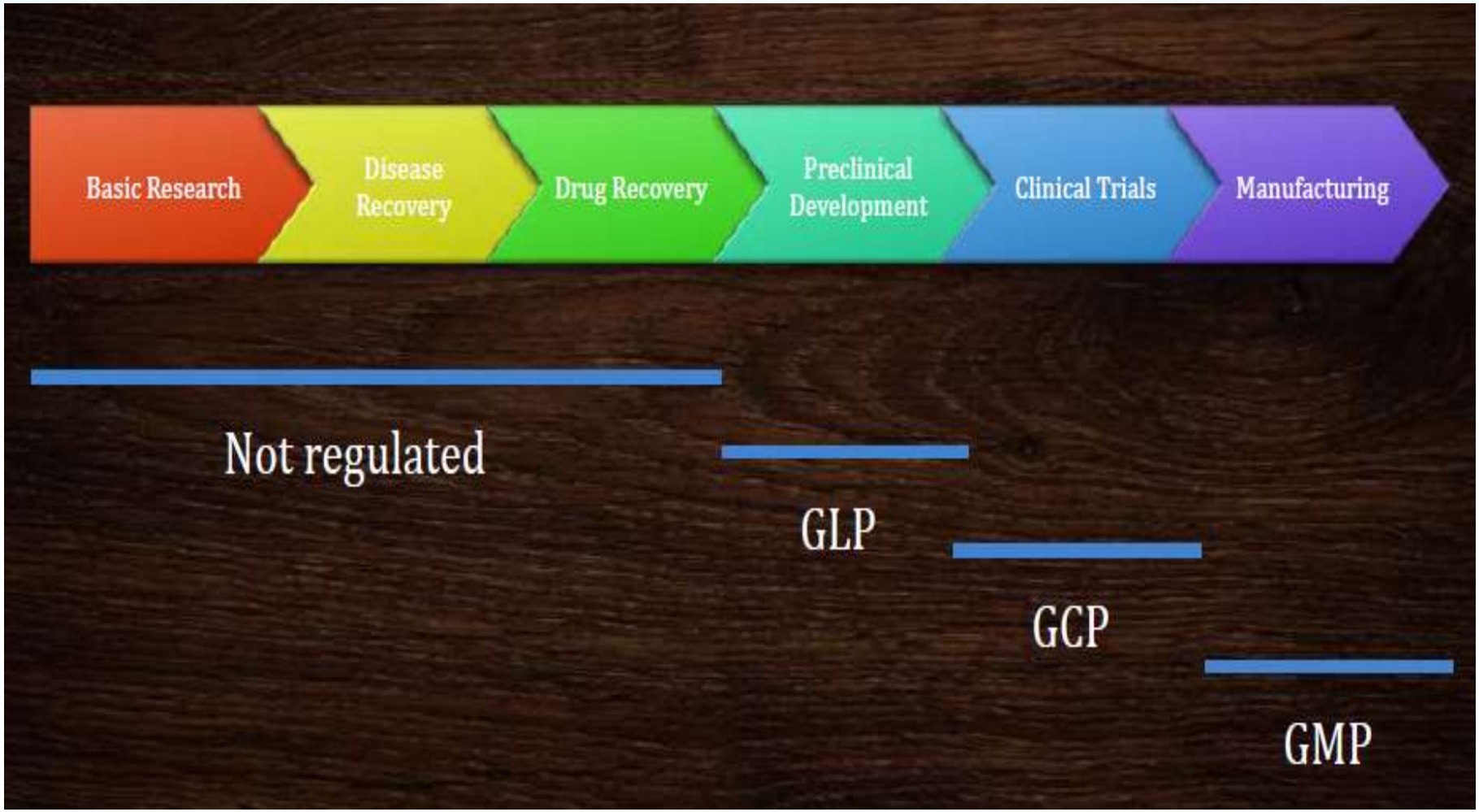

20th May
INTERNATIONAL
CLINICAL TRAIL
DAY
JAMES LIND
FATHER OF CLINICAL
RESEARCH
PAYING
TRIBUTE

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 .

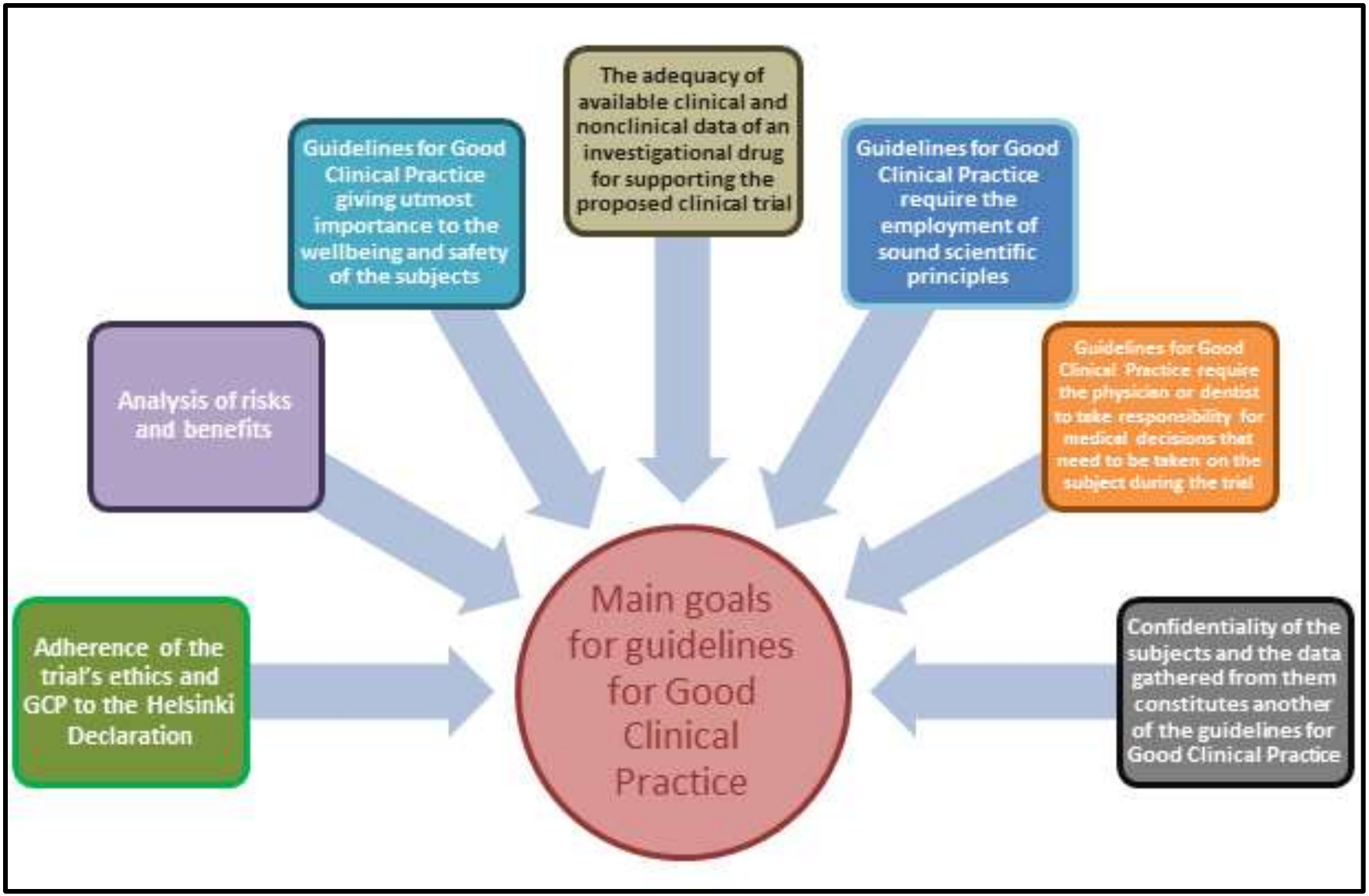
Thirteen Core Principles of GCP Guidance...continued

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.


The adequacy of available clinical and nonclinical data of an investigational drug for supporting the proposed clinical trial
Guidelines for Good Clinical Practice giving utmost importance to the wellbeing and safety of the subjects
Guidelines for Good Clinical Practice require the employment of sound scientific principles
Analysis of risks and benefits
Guidelines for Good Clinical Practice require the physician or dentist to take responsibility for medical decisions that need to be taken on the subject during the trial
Main goals for guidelines for Good Clinical Practice
Adherence of the trial's ethics and GCP to the Helsinki Declaration
Confidentiality of the subjects and the data gathered from them constitutes another of the guidelines for Good Clinical Practice

(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

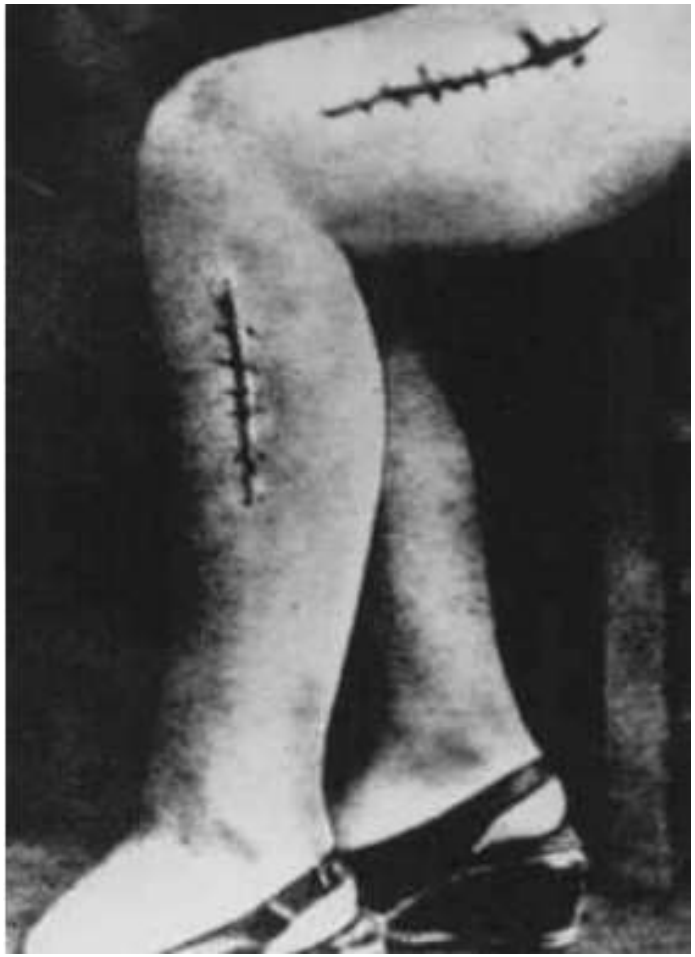
- Experiments conducted by Nazi physicians during World War II were unprecedented in their scope and the degree of harm and suffering to which human beings were subjected.

- Typically, the experiments resulted in death, disfigurement or permanent disability, and as such are considered as examples of medical torture.

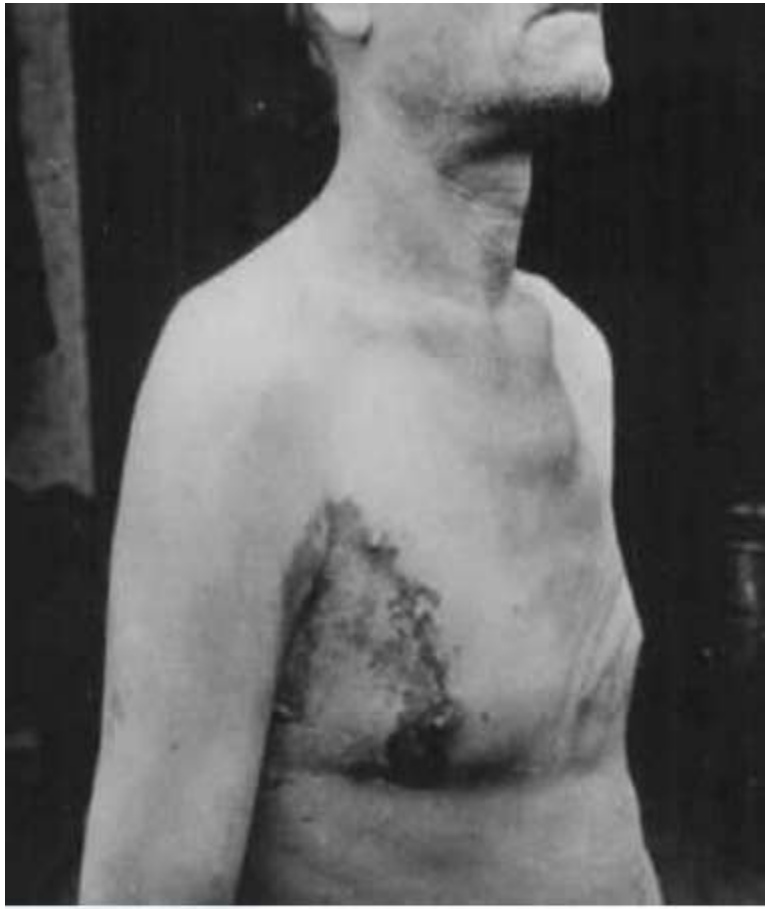
- "Medical experiments" were performed on thousands of concentration camp prisoners and included deadly studies and tortures such as-

  - ✓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.

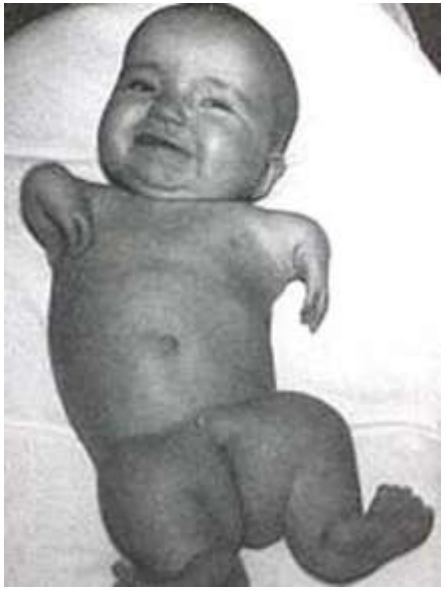
NUREMBERG CODE

- 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 distribu ted 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

Consent

Para 20 - The subjects must be volunteers and informed part icipants 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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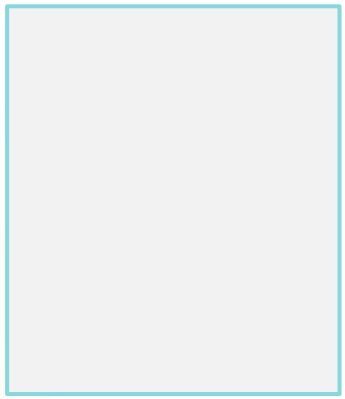

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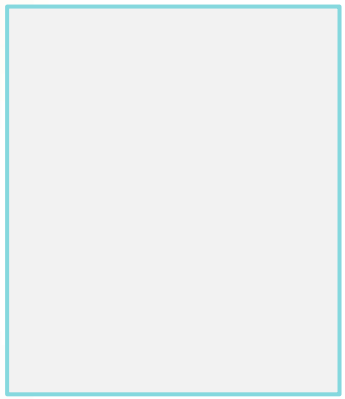

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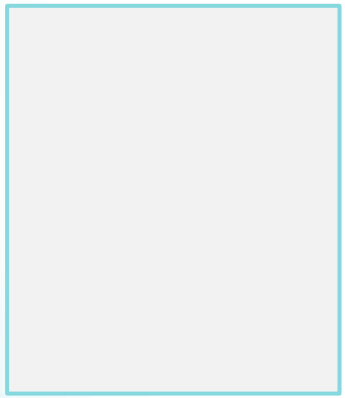

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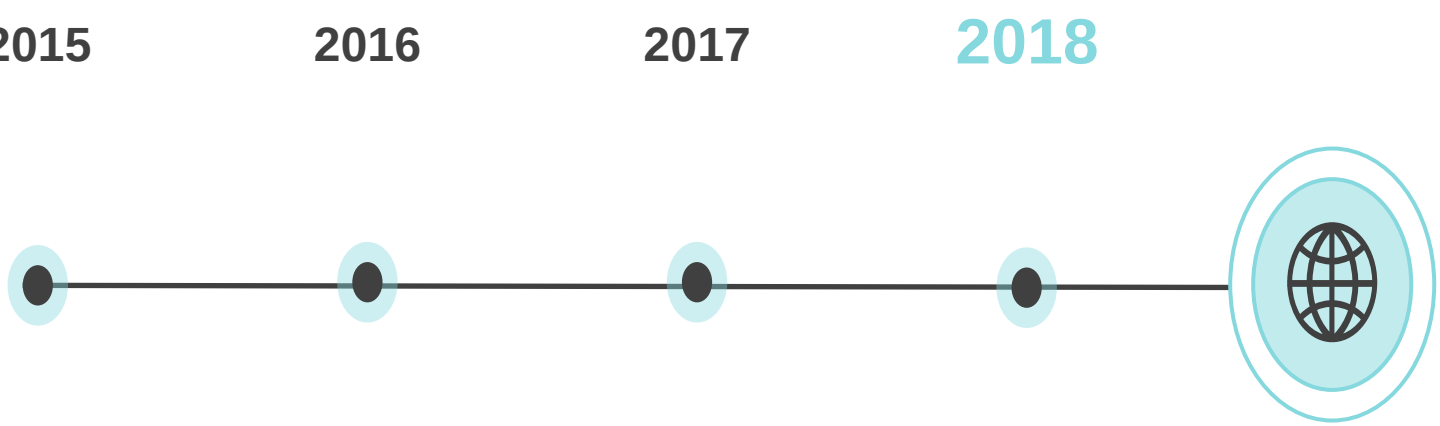

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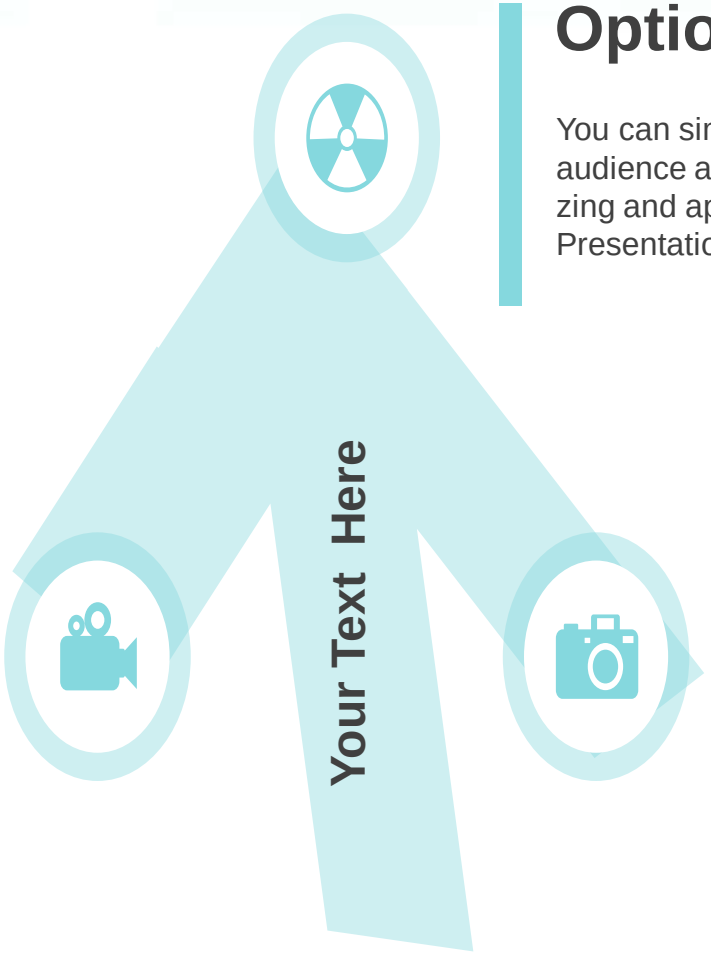

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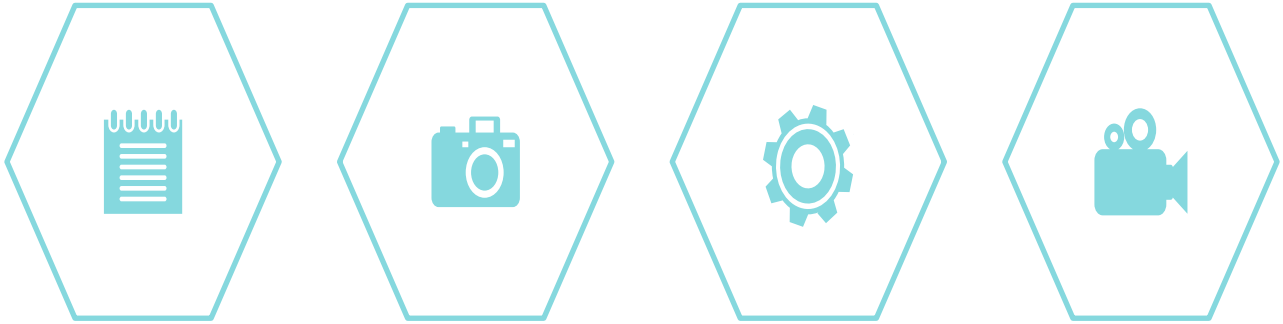

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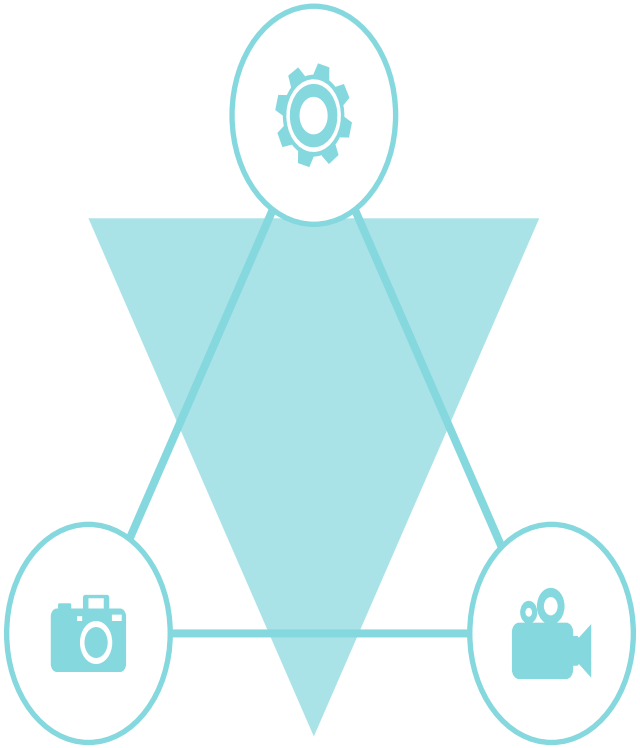

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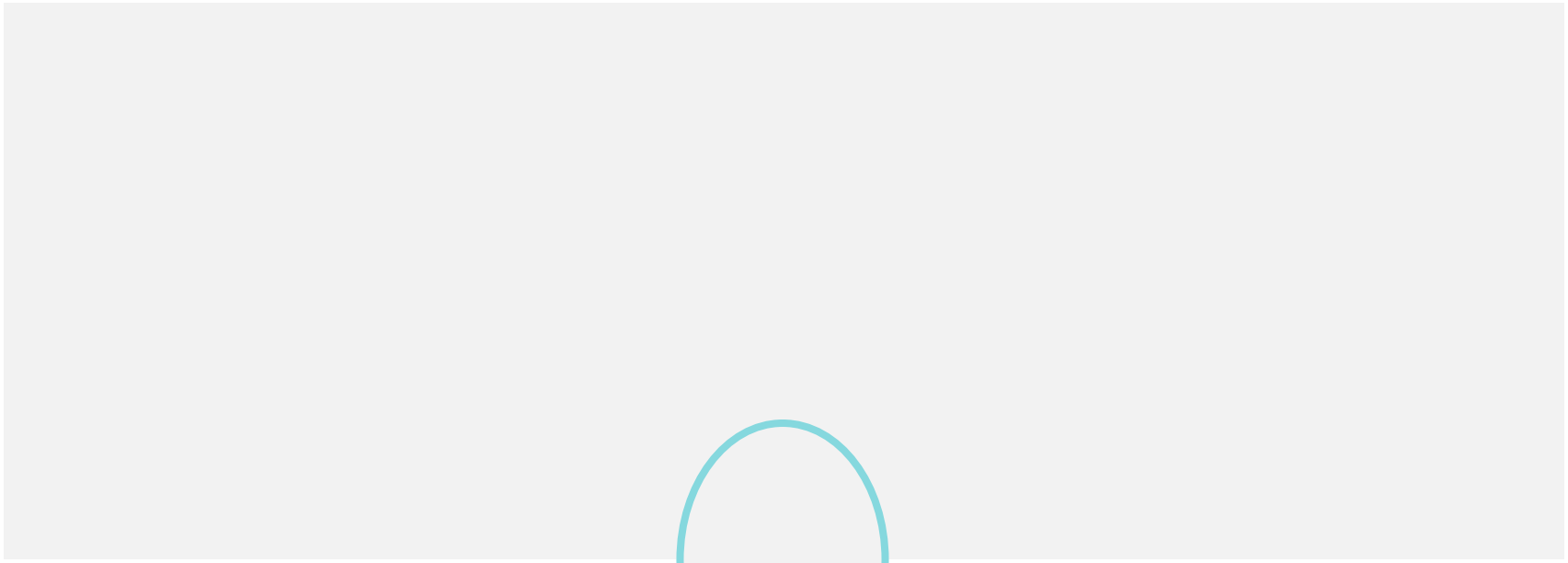

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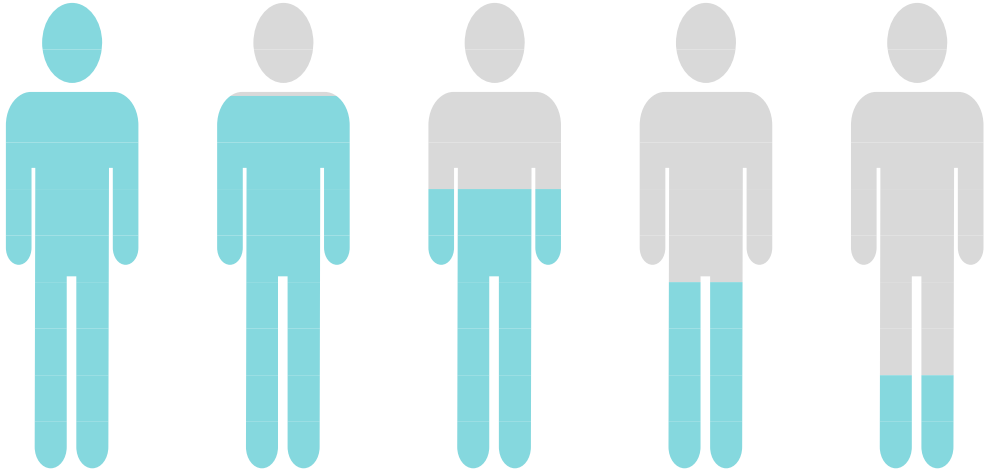

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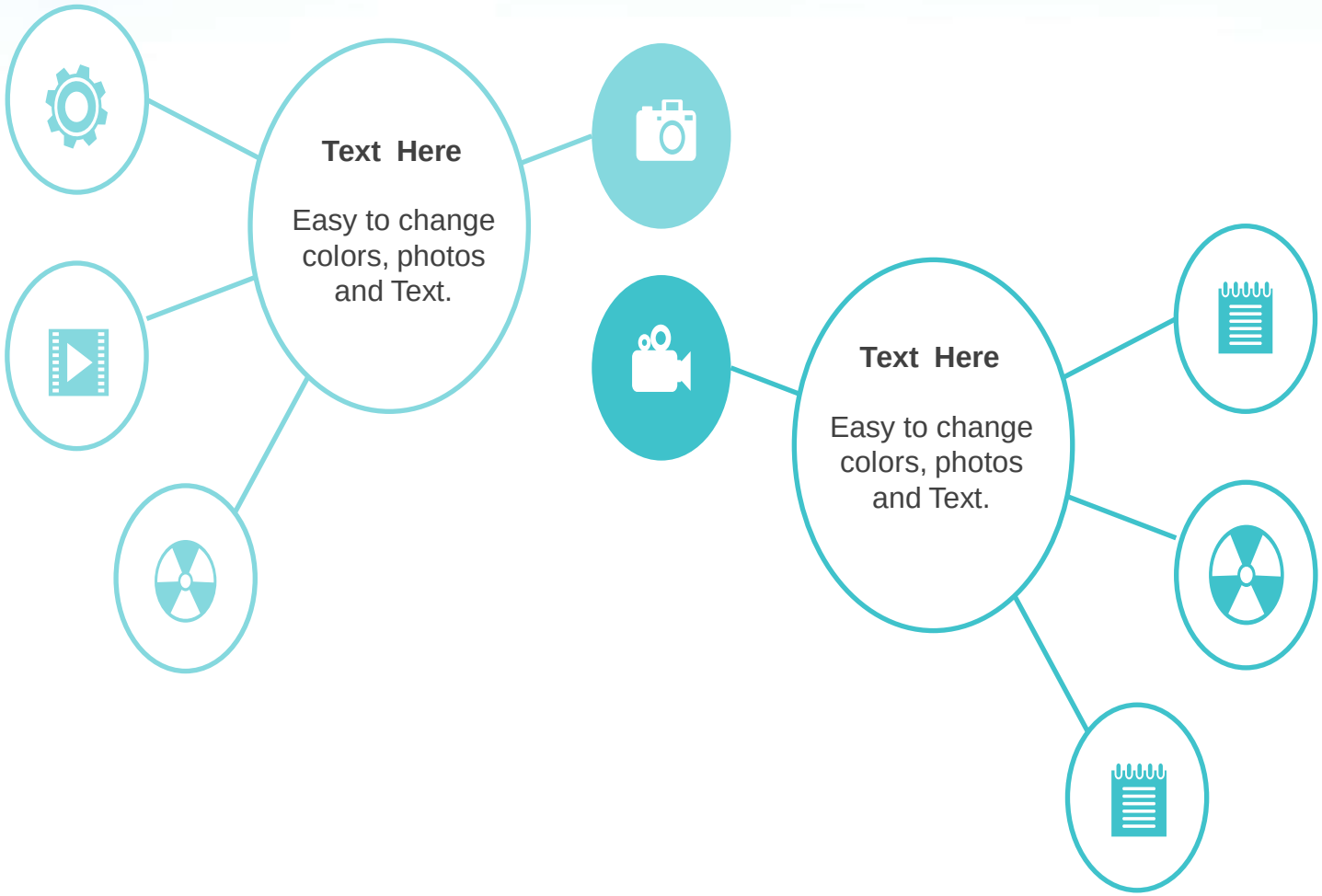

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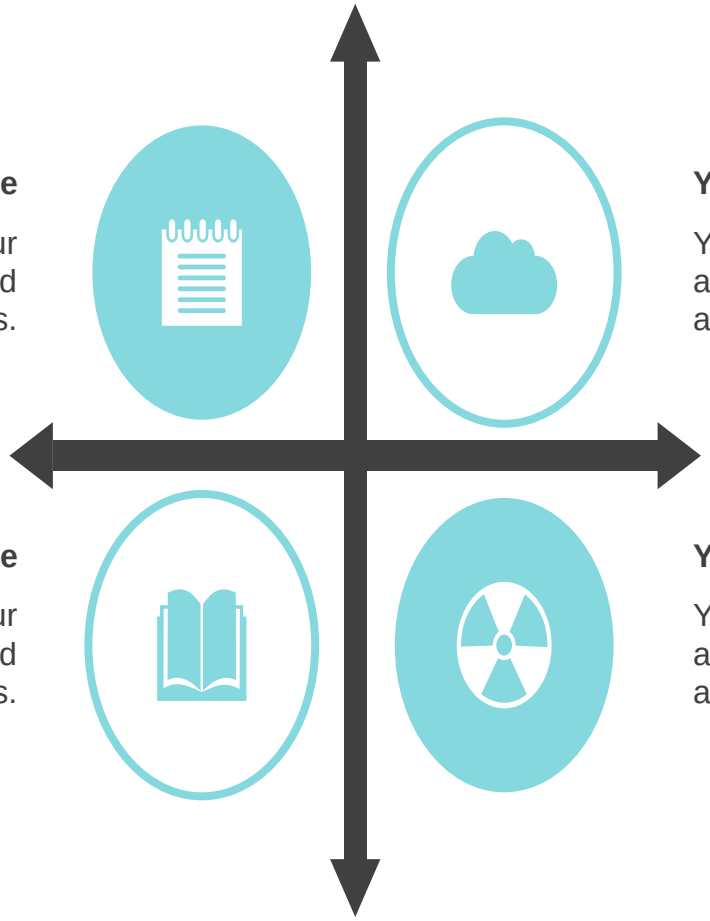

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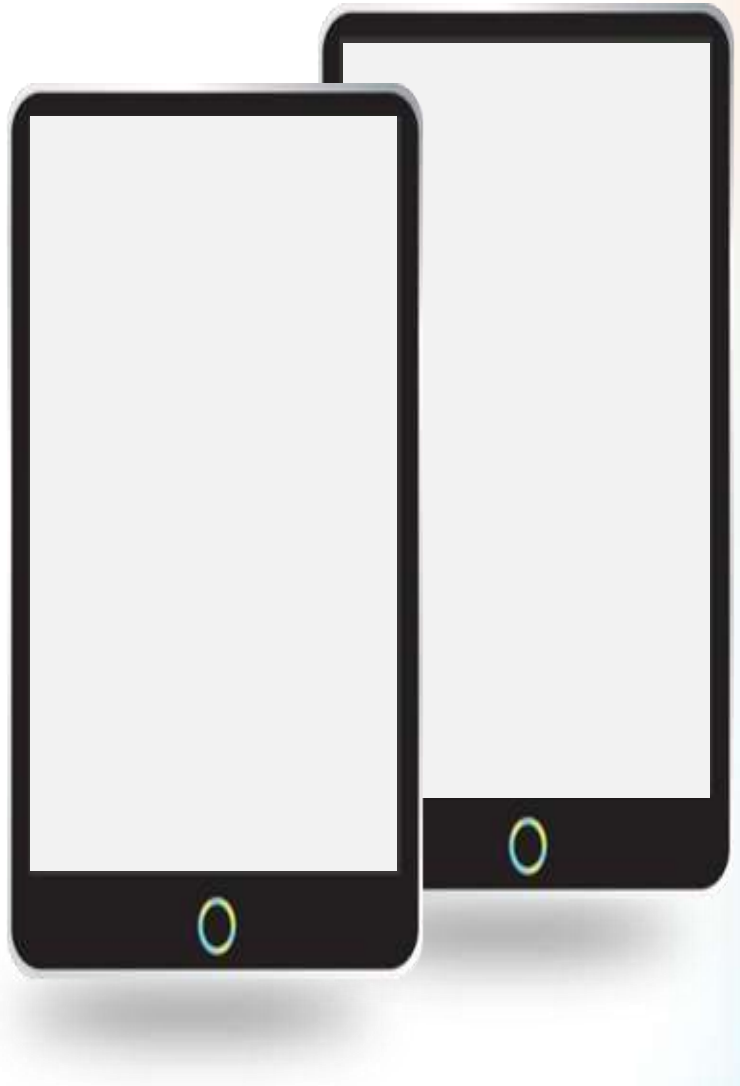

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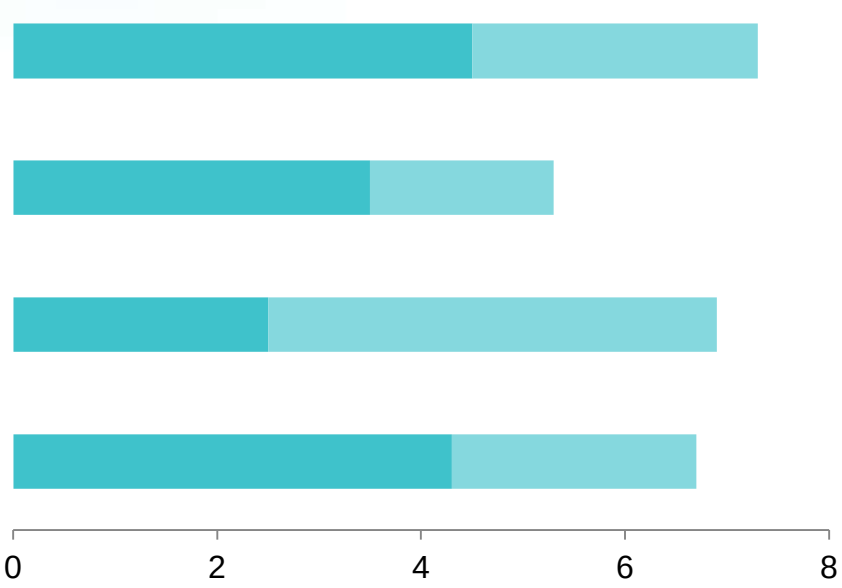

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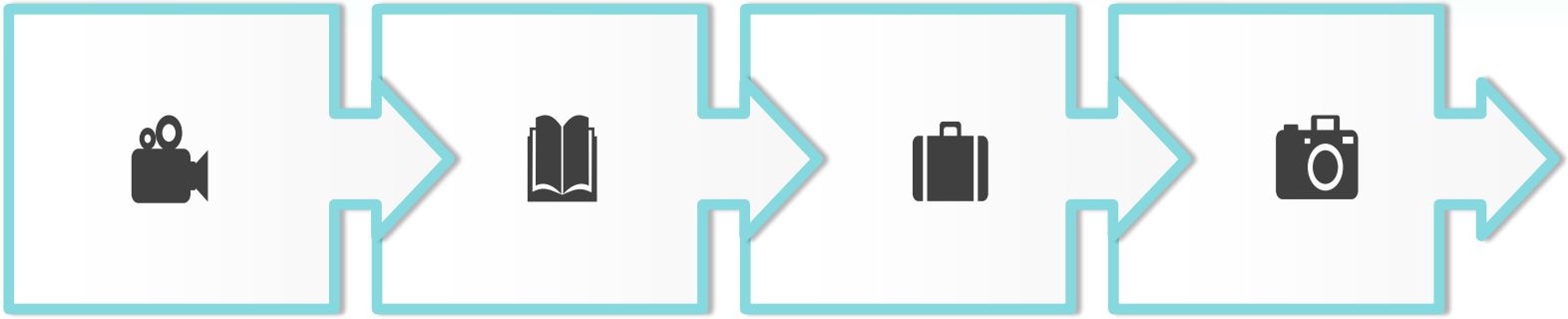

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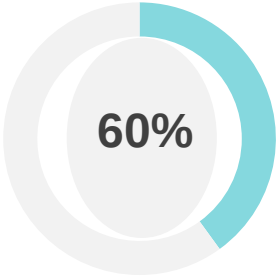

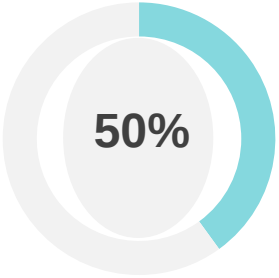

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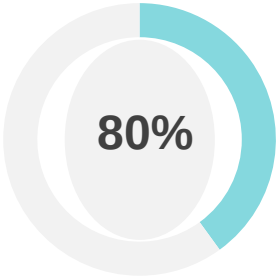

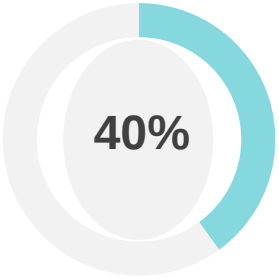

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Contents	Easy to change colors, photos and Text.				
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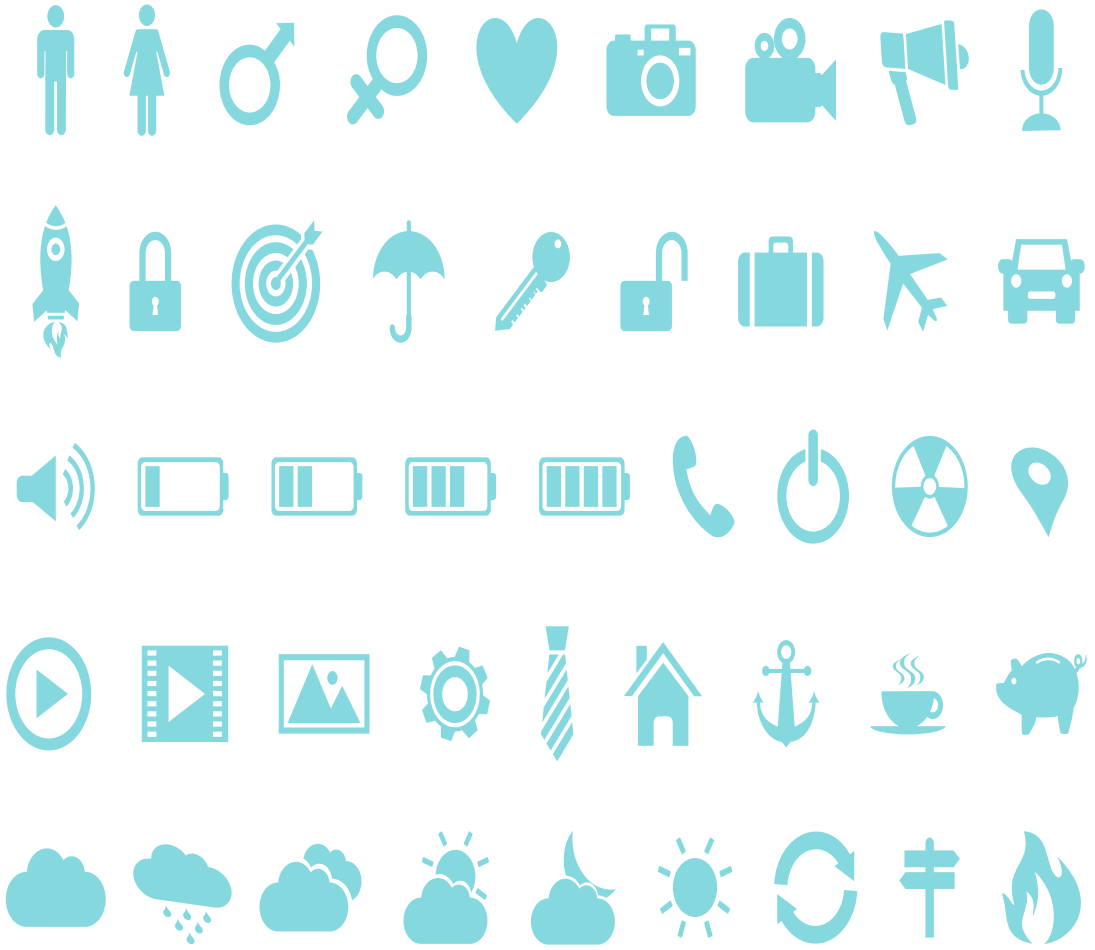

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