Q12

# Case study. Dr. Srinivasan is a senior scientist working for a reputed biotechnology company. He is heading a research team working on a new drug aimed at treating a rapidly spreading viral infectious disease. There is huge pressure to expedite the trials. Senior team members suggest shortcuts: manipulating data to exclude some negative outcomes, foregoing informed consent, and using compounds already patented by a rival company. Dr. Srinivasan is not comfortable taking such shortcuts, at the same time he realises meeting the targets is impossible without using these means. (a) What would you do in such a situation? (b) Examine your options and consequences in the light of the ethical questions involved. (c) How can data ethics and drug ethics save humanity at large in such a scenario?

UPSC Civil Services Mains 2024 · GS IV · 20 marks · Ethics Case Studies

Case Studies on above issues.

## Core demand of the question

- (a) What you would do as Dr Srinivasan: refuse the three shortcuts, record, escalate
- (b) Options and consequences against ethical questions of data, consent and patents
- (c) How data ethics and drug ethics protect humanity in a viral emergency

## Revision summary

Dr Srinivasan should refuse data manipulation, skipped consent and stolen compounds, lock the raw files, and escalate in writing.

Silent resignation leaves the protocol running; partial cheating is still fraud.

Lawful speed is adaptive design, more sites and honest timelines, plus a public-law path if a compound must be shared.

Data ethics keeps negative results visible so a million doses do not hide a harm.

Drug ethics - consent, committees, pharmacovigilance - is how a viral emergency stays medicine rather than an experiment on the unwitting.

## Introduction

Dr **Srinivasan** heads a **biotech** team on a **drug for a rapidly spreading viral disease**. Seniors want **speed**. The suggested means are **three crimes against persons**: **drop negative data**, **skip informed consent**, and **use a rival's patented compounds** as if they were **yours**. Targets are **impossible without the shortcuts**. This is **Helsinki versus a dashboard**, with a **virus** that will **not wait** and **patients** who **must not be used as fuel**.

## Body

### (a) What I would do

I would **refuse all three shortcuts in writing**, **the same day**, to the **seniors and to quality/regulatory**. I would **lock the raw data** so a **negative arm cannot vanish overnight**. I would **stop any protocol** that **enrols a person without consent**, and **treat an already enrolled unconsented person** as a **medical ethics emergency** (care, disclosure, report). I would **not import a rival's protected compound by theft**; if a **licence or a compulsory path** exists in a **true public-health emergency**, that is a **State and court file**, not a **lab swipe**. I would **put a realistic timeline on the table: what can be done lawfully in this many weeks**. I would **offer extra honest speed**: **adaptive design**, **more sites**, **shared data with public labs**, **night shifts**. If the firm **insists**, I would **escalate to the board, the CDSCO/ethics committee, and, if harm is imminent, a whistle channel**. I would **not resign in silence** while the **protocol continues**. **Nuremberg and Helsinki** are **not optional in a hurry**.

### (b) Options, consequences, ethical questions

**Option:** comply. Consequence: a **faster press note**, a **possible licence**, a **possible mass harm** when **hidden toxicity** meets a **million doses**, **criminal and professional ruin**, and a **virus still mutating. Ethical questions: persons as means** (Kant), **fraud** as **policy**, **theft** as **innovation**. **Option:** partial cheat (only drop a few outliers). Consequence: the **same fraud with a milder story**; **regulators** can still **find the raw files**; **self-deception**. **Option:** quit and stay silent. Consequence: **clean hands, dirty drug**. **Option:** refuse, document, propose a lawful crash programme, whistle if blocked. Consequence: **career risk**, **possible delay**, **a trial that can be trusted**, **patients who chose**. **Consent** is **autonomy**; skipping it is **assault dressed as care**. **Data integrity** is **justice to future patients** who will **take the pill**. **Patent theft** is **not Robin Hood** if it **also skips safety**; a **compulsory licence** is the **public-law** cousin, **not a fridge raid**. **Virtue:** courage is **the mean** between **cowardly fraud** and **vain delay**. **Gandhi: means**. A **cured statistic** built on **unwitting subjects** is a **plague of another kind**.

### (c) Data ethics and drug ethics saving humanity

**Humanity** in a **viral wave** is saved by **interventions that work**, not by **interventions that look like they work**. **Data ethics** (FAIR-enough honesty, **no p-hacking**, **pre-registration**, **negative results published**) stops a **second wave of iatrogenic death**. **Drug ethics** (**preclinical sense**, **independent ethics committee**, **informed consent**, **equipoise**, **pharmacovigilance**, **recall power**) stops a **thalidomide-class** story in a **new font**. Together they **protect the trial subject** and the **unborn taker**. In an **emergency**, **ethics accelerates by dropping vanity**, not by **dropping the person**: **platform trials**, **real-world evidence with consent**, **data sharing** among **labs that are rivals in peace**. **Humanity** is also **the rival firm's patients**; **stolen compounds without a licence** can **collapse the incentive to invent the next antiviral** - a **utilitarian** cost - while **honest pooling** can **save**. The **civilisational lesson** of **Nuremberg, Tuskegee, and Ujjain-type** wounds is that **speed without consent** is **how medicine becomes an occupying army**. Data and drug ethics are **how a republic stays a hospital**.

### Flow diagram

Viral urgency -> Cheat or honest speed

Cheat or honest speed -> No fake data no skipped consent no theft

No fake data no skipped consent no theft -> Adaptive trial licence path

Data ethics -> Trusted drug

Drug ethics -> Trusted drug

## Conclusion

Refuse the data wipe, the skipped consent and the stolen compound; write it down and offer every lawful form of speed. A viral emergency makes honesty more necessary, not less. Humanity is saved by drugs that are true, not by dashboards that hid the dead.

## Facts & figures

### Declaration of Helsinki

The core statement that medical research on humans needs consent, independent review, and that the subject is not a mere means to science.

### Informed consent

A person's understood, voluntary agreement to a trial; skipping it in a hurry is an ethics and often a legal failure, not a technical shortcut.

### Data integrity

Raw results, including negative ones, must remain reconstructable; dropping outcomes to hit a target is scientific fraud.

### Compulsory licensing

A public-law route in some emergencies to use a patented invention on terms; it is not the same as secretly using a rival's compound in a lab.

### Clinical equipoise

The honest uncertainty that justifies putting a person in a trial arm; fake data destroys the justification itself.

### Pharmacovigilance

Watching a drug after approval; it only works if the pre-approval file was not a fiction.