

## Regulatory & Ethics — HIPAA GDPR and Consent in PGx — Hands-on

Explore the regulatory and ethics landscape around pharmacogenomics programs. This module focuses on core ideas from HIPAA, GDPR and consent frameworks, and how governance, roles and documentation help teams run PGx initiatives in a responsible and compliant way.

### Regulatory & Ethics — HIPAA, GDPR & Consent in PGx

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#### Session 1

**Fee: Rs 8800** [Apply Now](#)

#### Regulatory Landscapes & Data Protection Concepts

Why pharmacogenomics raises specific regulatory and ethics questions

[genomic sensitivity and long term impact](#) [family and group level implications](#) [clinical vs research use of PGx data](#)

High level view of key regulatory families

[health privacy and security themes](#) [laboratory and](#)

**quality regulations idea** **institutional policies and ethics review**

Core data protection concepts used across frameworks

**identifiers and de identification thinking** **purpose limitation and minimisation ideas** **accountability and documentation themes**

## **Session 2**

**Fee: Rs 11800** Apply Now

### **HIPAA, GDPR & Governance for PGx Data**

HIPAA style perspectives on health information

**protected health information notions** **role based access control ideas** **audit trail and breach response themes**

GDPR style perspectives on personal and sensitive data

**lawful bases and special category data** **data subject rights at high level** **data protection impact assessment idea**

Designing a simple governance structure for PGx programs

**steering group and working groups** **roles for clinicians labs and IT teams** **policies standard operating procedures and logs**

## **Session 3**

**Fee: Rs 14800** Apply Now

### **Consent, Reporting & Patient Communication**

Concepts for informed consent in pharmacogenomics

**clarity of purpose and scope** **future use and data sharing options** **re contact and withdrawal themes**

High level ideas for communicating PGx results

**plain language drug and gene summaries** **avoiding deterministic phrasing** **supporting shared decision making**

Handling secondary findings and family implications conceptually

**distinguishing primary and incidental results** **family communication challenges** **role of ethics and counselling support**

#### **Session 4**

**Fee: Rs 18800** Apply Now

### Mini Capstone: PGx Governance Charter & Checklist

Select a PGx use case and sketch a governance charter

**describe scope and clinical context** **list key roles and responsibilities** **outline decision and escalation paths**

Draft a concise ethics and compliance checklist for PGx teams

**data protection and access controls** **consent documentation and renewal** **incident response and reporting lines**

Deliverables: PGx governance one pager and checklist template

**PDF or DOCX summary** **checklist for local adaptation** **starting point for ethics discussions**