



Finding common ground: Patient Safety, Quality Assurance and Data Integrity

09MAY2025



Introduction

Patient
Safety

+

Drug
Quality

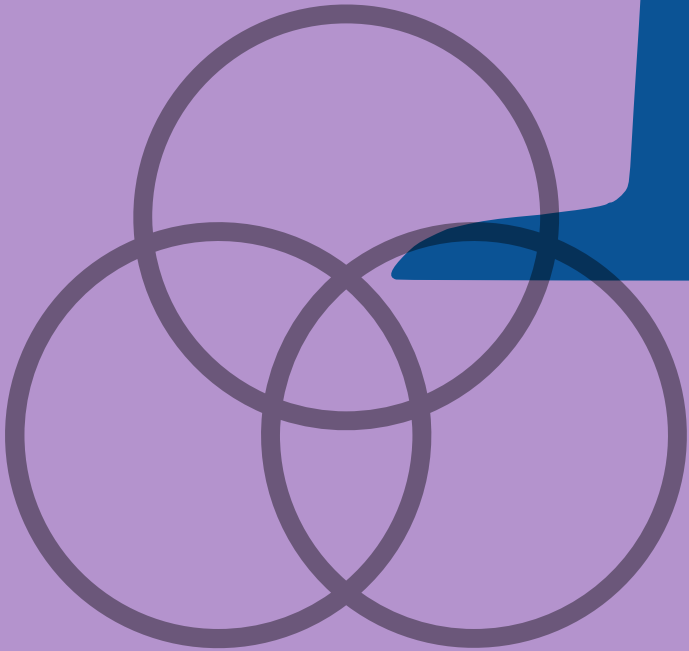
+

Data
Integrity

=

Unified
Goal

Foundation



History

Harmonization

Ethics

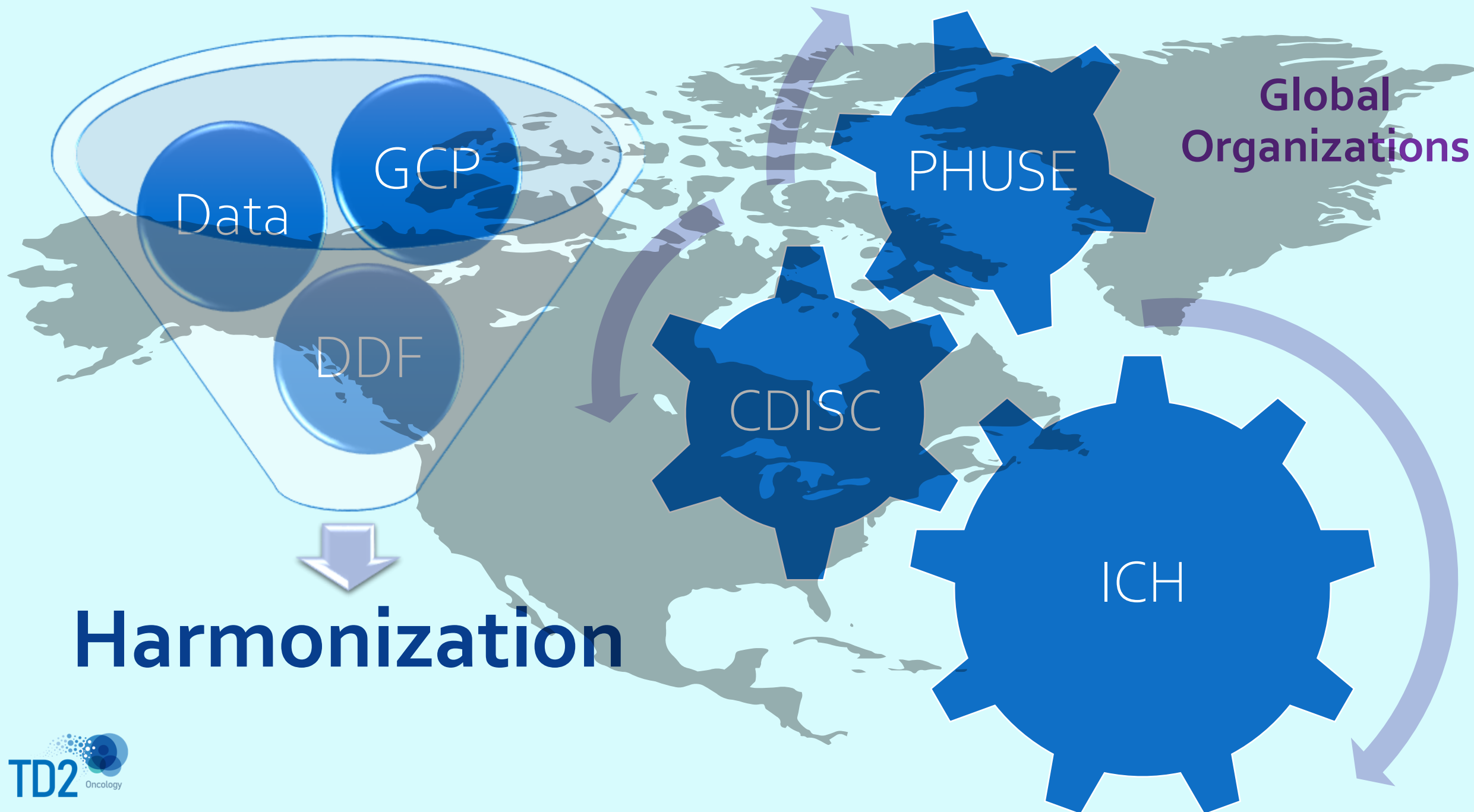
History

Lessons Learned

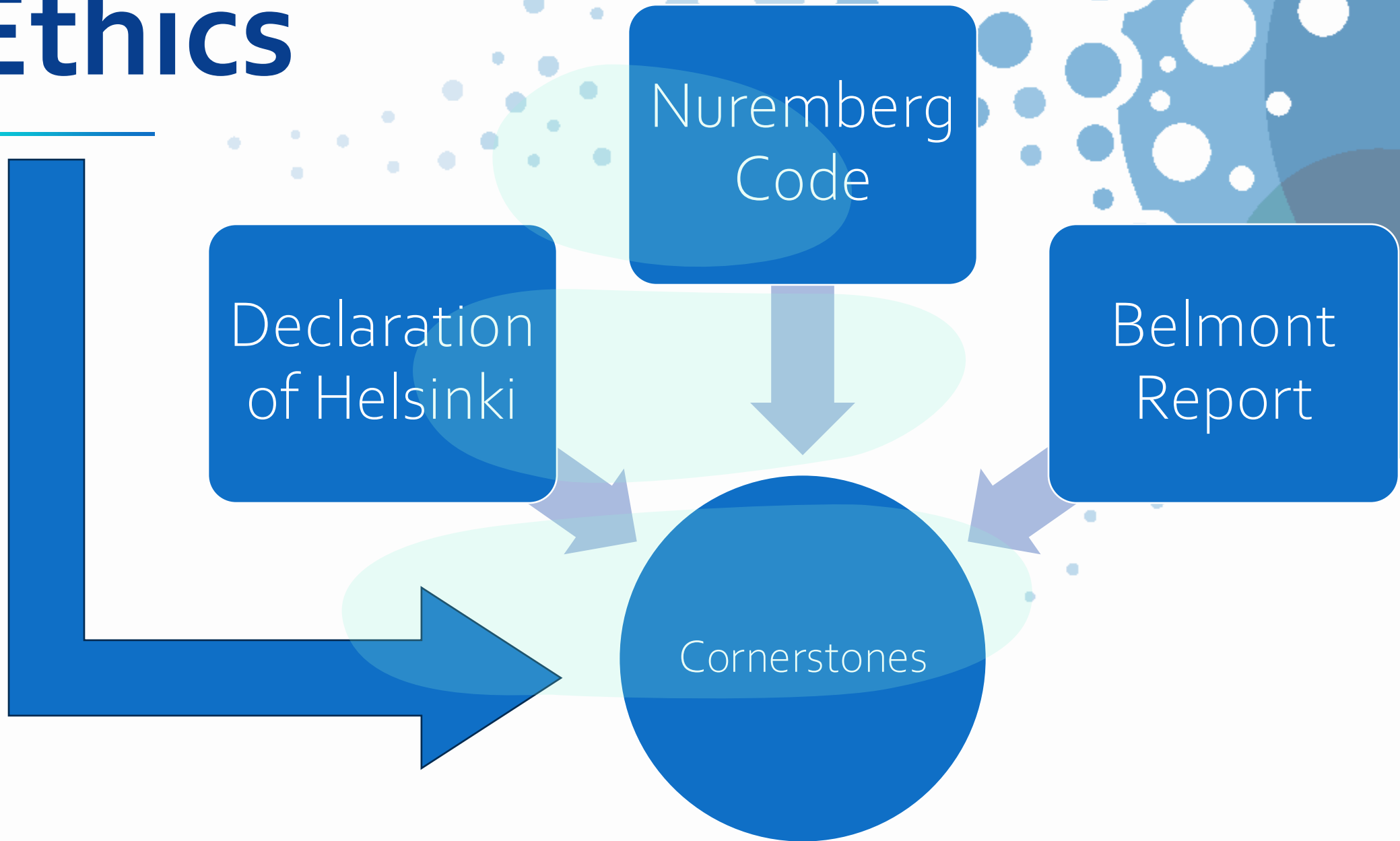
WWII – Informed consent

Tuskegee Experiment – Untreated Syphilis Study

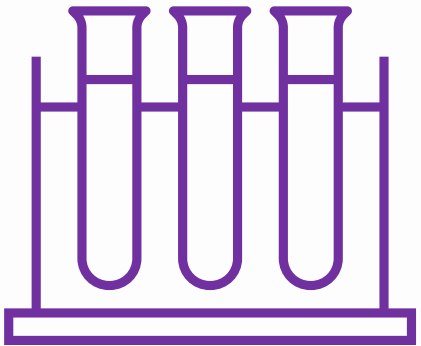
Thalidomine Tragedy



Ethics



Prevailing Opinion



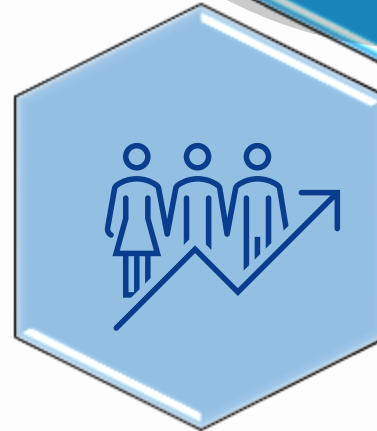
Security



ICH EG
(R₃)

Trail
Participants

Data
Privacy



RBQM

Mitigation

Our Responsibility

Ethical Conduct



HONESTY



RESPECT



FAIRNESS

Our Responsibility

Regulations



KNOW



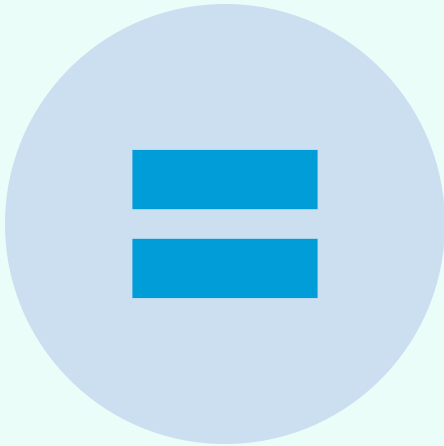
IMPLEMENT



ENSURE

Our Responsibility

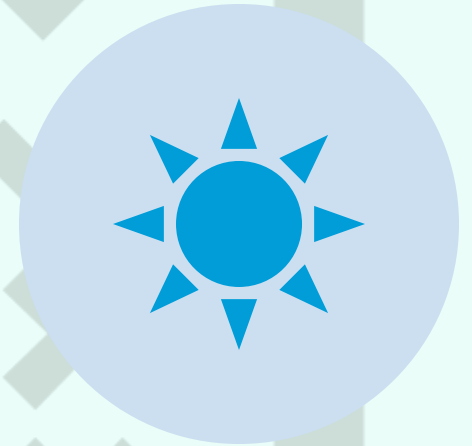
Quality



ACCURACY

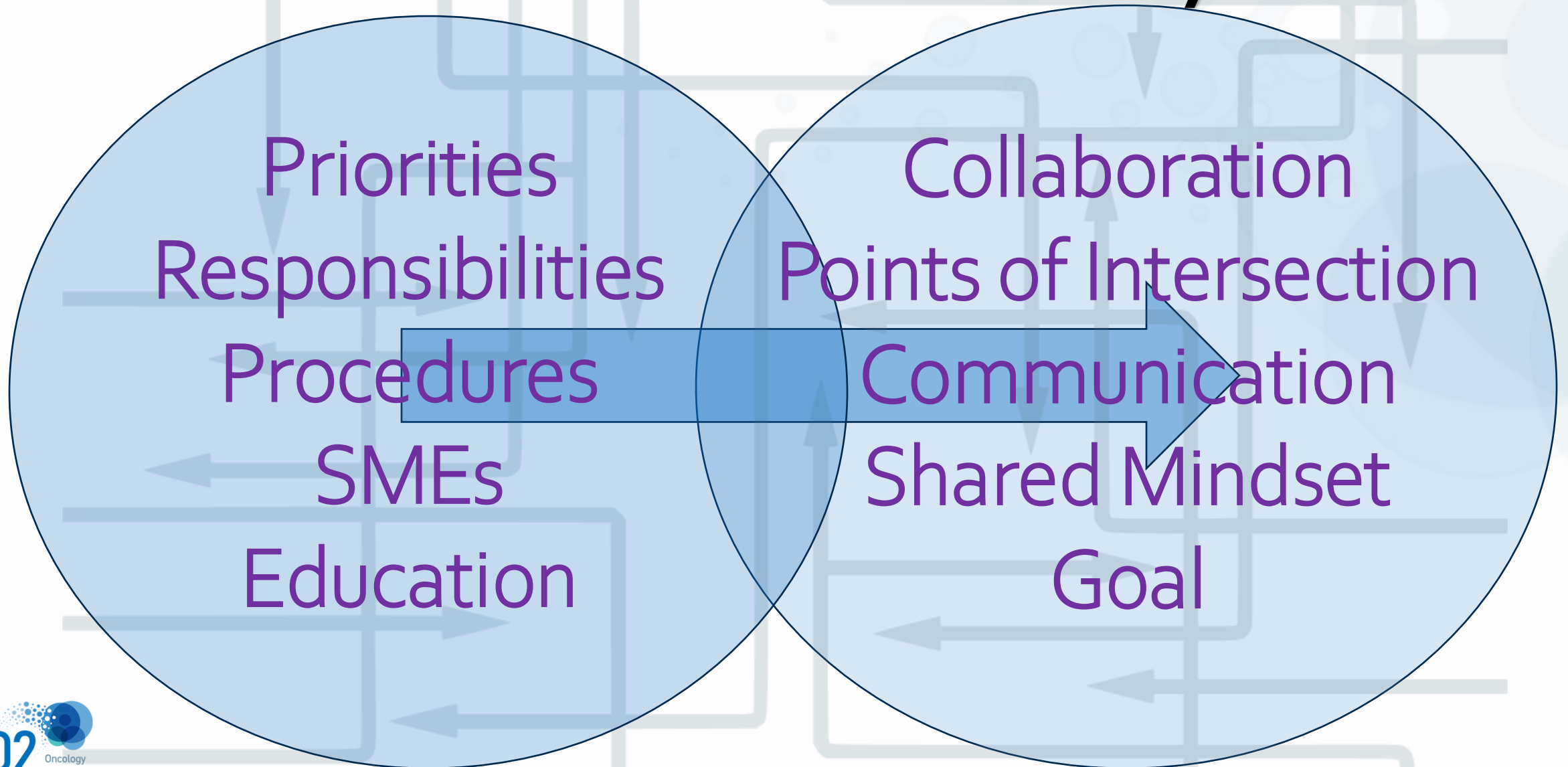


COMPLETE



ORIGINAL

Clinical Research Roles and Dynamics



Q&A

