HOW PHYSICIANS DECIDE:
A REGULATORY COMPLIANCE PERSPECTIVE FROM CLINICAL RESEARCH

Fraser Smith

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Fraser Smith
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Declaration:

I declare that this Doctorate of Business Administration thesis is my own work and that all critical literary and electronic sources have been properly acknowledged, as and when they occur, in the body of the text.

No portion of the work referred to in this thesis has been submitted in support of another application for a degree or qualification of this, or any other, university or institute of learning.

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Abstract:

The central aim of this thesis is to investigate how physicians, working for Pharmaceutical Product Development (PPD), a clinical research organisation (CRO), make decisions for a new industry standard for good clinical practice in medical device trials. This topic is introduced via review of decision theory and decision-making (DM) in contextual environments. Physician's career experiences, insights and perceptions of how they make regulatory compliance decisions, and how they think these new requirements should be met, are explored in the main study.

The research rationale relates to the author's experience of physician DM in non-medical settings during 25 years working in the field, with a desire to ascertain how compliance influences are identified, assessed and synthesized into decisions within the workplace. Furthermore PPD physicians hold senior positions and new industry regulations require regulatory compliance decisions to be made at the highest level.

In this study an interpretive phenomenological paradigm was used to ascertain how physicians make sense of industry regulation then make compliance decisions based on their roles, experiences, cues and sources of data available. Literature review identified 4 core themes (decision-making, errors, situation awareness and new requirements) that guided qualitative data collection via 2 mini-focus groups (n=3 per group) and semi-structured interviews (n=12). Review of 18 physicians' data occurred via framework analysis then comparing between contrasting positions presented. The findings found 4-5 dimensions under each core theme from which 2 frameworks were constructed: firstly, using DM tenets to guide physicians' DM in context and, secondly, identifying how to comply with new industry requirements.

This research contributes to academia and practice via framework generation for DM in context. It is unique in its contextual exploration, analysis and interpretation of physicians' impressions, from departmental heads to company board members, in relation to their everyday working lives and the decision approaches used to ensure regulatory compliance within their organisational area of responsibility. The thesis ends by considering potential areas for further research such as deploying each framework, applying the framework concepts with other industry legislation changes or exploring alternative research paradigms in PPD.

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ACRO	Association of Clinical Research Organisations
AIMDD	Active Implantable Medical Device Directive
ASQ	American Society of Quality
BSI	British Standards Institute
CAPA	Corrective and Preventative Action
CCC	Corporate Compliance Committee
CCT	Cognitive Continuum Theory
CDM	Classical Decision-Making
CE	*Communauté Européenne* is a mandatory conformity marking for medical device products sold within the EEA since 1985
CEO	Chief Executive Officer
CEST	Cognitive-Experiential Self-Theory
CIHNAL	Cumulative Index to Nursing and Allied Health Literature database
CIOMS	Council for International Organizations of Medical Sciences
Class I	medical device classification subject to least regulatory control
Class IIa	medical devices subject to special controls – lower patient risk
Class IIb	medical devices subject to special controls – increasing risk
Class III	medical devices subject to special controls – highest risk
CRF	Case Report Form
CRO	Clinical Research Organisation
CRRM	Clinical Rapid Response Mechanism
C-suite	Company's most important top level executives
CTMS	Clinical Trial Management System
DBA	Doctor of Business Administration
Declaration of Helsinki:	Recommendations guiding medical doctors in biomedical research involving human subjects
DIA	Drug Information Association
DM	Decision-making
DynaMed	Clinical reference tool created by physicians for physicians, for use at the point-of-care. Monitors content of > 500 medical journals on a daily basis.

EBM	Evidence-Based Medicine
EEA	European Economic Area
EMA	European Medicines Agency
Embase	An international biomedical database
ePocrates	Suite of mobile health software applications for clinical content & decision support at the point of care covering drug, disease & diagnostic content.
FA	Framework Analysis
FDA	Food and Drug Administration (US)
FTT	Fuzzy Trace Theory
GCP	Good Clinical Practice
GxP	Good **x** Practice guidelines (where x = industry quality specific)
H-DA	Hypothetico-Deductive Approach
ISO	International Organisation for Standardisation
ISO14155:20111	International Standard for ensuring good clinical practice within medical device trials in humans
IT	Image Theory
MDD	Medical Devices Directive
MDM	Medical decision-making
Medline	Medical Literature Analysis and Retrieval System Online – bibliographic database of life sciences & biomedical information
MHRA	Medical and Healthcare Products Regulatory Agency (UK)
MFG	Mini Focus Group
NDM	Naturalistic Decision-Making
Pharma	Pharmaceutical manufacturing company
PPD	Pharmaceutical Product Development Inc.
Q&As	Question and answers
QC	Quality control / check
QMS	Quality Management System
Preclarus	PPD clinical database that consolidates and standardizes study data from multiple sources in real-time with transparent reporting capabilities needed to enable critical go, no-go decisions
RCDC	Rapid Clinical Decision in Context model
RISC	Regulatory Intelligence Steering Committee

RM	Recognition-Metacognition model
RPD	Recognition - Primed Decision- making model
RQA	Research Quality Association
SA	Situation assessment
SAE	Serious Adverse Event
SDM	Shared Decision-Making
SME	Subject Matter Expert
SRK	Skills-based, Rules-based, Knowledge-based model
SSI	Semi - Structured Interview
SWOT	Strengths, Weaknesses, Opportunities and Threats
TPB	Theory of Planned Behaviour
TRA	Theory of Reasoned Action
TTM	Trans-Theoretical Model
TRREE	**T**raining and **R**esources in **R**esearch **E**thics **E**valuation program
UK	United Kingdom and Northern Ireland
UpTo-Date	evidence-based clinical decision support resource to help make decisions at the point of care. Only resource of its kind associated with improved outcomes.
US	United States of America
WHO	World Health Organisation
WMA	World Medical Association

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