A MODEL AND GUIDE FOR BLOOD COAGULUM-OMICS

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The NHS will be a world-leading healthcare organization to predict and diagnose inherited and acquired disease, and to personalize treatment and intervention. This program was designed to validate and quality manage the introduction of Blood Coagulum-OMICS and verify genomic, viscoelastic, and proteomic predictive value for hemostasis and thrombosis.

Background: In 2014, a Patient Blood Management program was overseen by a national governance representative, sponsored by an anesthetic lead and edited by an MHRA inspector who stated "this program is suitable for the NHS". In 2017, that program was posted to the hemostasis and thrombosis, National External Quality Assurance Scheme and then to the British Blood Transfusion Society, in the UK.

Study: The conclusion read as "scientific specialists are now firmly planted in the realms of clinical effectiveness, interfacing clinicians on the governance board. We must now accelerate the PBM Quality Assurance network to control risk from genomic and proteomic explosions in personalized medicine. Quality assures our technological advances from end to end of the surgical examination phase and control our pharmacological breakthroughs in support of healthcare clinicians.

Program Development: On the 4th of July 2017, Professor Dame Sally, the Chief Medical Officer of the UK called on the NHS to provide access to genomic sequencing, as standard. This followed studies that realised genome models to pre-empt a bleed or thrombotic event. Meanwhile coagulation and fibrinolysis elasticity reference ranges to monitor a clinical event or target a therapy are developing, at a time when coagulation proteomics have passed proof of concept.

Conclusion: This second program on Blood Coagulum-OMICS was designed to stop the bleed and thrombotic event by improving the predictive value in pre-examination and examination phases. A program for Blood Coagulum-OMICS is a minimum standard for haemostasis and thrombosis and requires consideration by the International Organisation for Standardisation.

ISO. STD	REVISED	INTERNATIONAL ORGANISATION FOR STANDARDISATION: TITLE
10005	2005	QMS – Guidelines for Quality Plans
14155	2011	Clinical Investigation of Medical Devices for Human Subjects – GCP *
15189	2012	Medical Laboratories – Requirements for Quality and Competence
27001	2013	Information Security Management Systems - Requirements
13485	2016	Medical Devices – QMS – Requirements for Regulatory Purposes
31010	2009	Risk Management – Risk Assessment Techniques
18113	2009	Specific Requirements for Info. Supplied by the Manufacturer of IVD reagents
14791	2012	Risk Management for Medical Devices
22870	2016	Point of Care Testing (POCT) – Requirements for Quality and Competence
17043	2010	Conformity Assessment – General Requirements for Proficiency Testing
9000	2015	QMS – Fundamentals and Vocabulary
90011	2011	Guidelines for Auditing Management Systems
17011	2017	Conformity Assessment General Requirements for Accrediting Conformity

*Excludes IVD Medical Devices [This excludes viscoelasticity. An application to spectral proteomics is unknown]

Table 1. List of ISO standards in a Blood Coagulum-OMICS program

Biography

James Henry completed his Master of Science (Upper Merit) in 2009 from Middlesex University U.Kin Molecular Pathology. Also he completed his Master of Science (Distinct) in 2014 from University of Greenwich U.K in Patient Blood Management Quality Systems. In 2014 a Patient Blood Management program was overseen by a U.K national governance representative, sponsored by an anesthetic lead and edited by an MHRA inspector who stated "this program is suitable for the NHS". In 2017 that program was posted to the National External Quality Assurance Scheme and then to the British Blood Transfusion Society. In 2018, ISO published the "Quality of an organization — Guidance to achieve sustained success". The author of "Blood Coagulum-OMICs" has developed a model for hemostasis and thrombosis genomic pre-exams and a viscoelastic & proteomic examination to improve predictive value in personalized and regeneration medicine

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