Ethics assessment and Guidance in Different Types of Organisations

Standards, certification and accreditation organisations

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Annex 3.i
Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries
Deliverable 1.1

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Contents

1. Introduction

This report looks at some organisations that focus on developing standards, certification and/or accreditation of ethical research, R&D organisations and professionals, involved in research and innovation. The scope of this report is limited, it does not scope out the entirety of the standards, certification and accreditation landscape, rather, it provides a brief overview of the standards, certification and accreditation organisations (some of which represent established formalised bodies, and others that are relevant but less formalised). The report is based on desktop research and draws insights from discussions with the Netherlands Standardization Institute.

2. Basic description

A standards organisation, standards body, standards developing organisation (SDO), or standards setting organisation (SSO) is any organisation whose primary activities are developing, coordinating, promulgating, revising, amending, reissuing, interpreting, or otherwise producing technical[1] and non-technical standards that are intended to address the needs of some relatively wide base of affected adopters.[2] Most standards are voluntary in the sense that they are offered for adoption by people or industry without being mandated in law. Some standards become mandatory when they are adopted by regulators as legal requirements in particular domains.[3] The most influential standards organisation is the International Organization for Standardization (ISO). At the EU level, there are three organisations that constitute the European Standards Organizations (ESOs) that are officially recognised by the European Commission and act as a European platform through which European Standards are developed. They are CENELEC (European Committee for Electrotechnical Standardisation), ETSI (European Telecommunications Standards Institute) and CEN (European Committee for Standardisation) which covers technical standards beyond the electrotechnical and telecommunications domains.

Certification organisations are independent entities that provide an assurance that a product, service, system or organisation meets specific requirements.[4] Certification may be provided with, or without a seal (i.e. a symbol or mark that graphically demonstrates or certifies that a product, service, system or organisation meets specific requirements). Accreditation organisations generally are organisations or bodies that provide formal recognition that certification bodies operate according to accepted (international) standards.[5] This explanation applies more lightly to some of the accreditation providing organisations discussed in this report as the nature of their activities is slightly different.

There are no organisations that indulge specifically and solely in setting 'ethical standards' or in conducting ethical assessment. Based on a literature review and online search, this report identifies a number of different types of organisations that are relevant to SATORI since they directly or indirectly cover ethical aspects in some of their activities – the full list of analysed organisations is provided in the Annex.

[1] Wikipedia, "Technical Standard". https://en.wikipedia.org/wiki/Technical_standard
[2] Wikipedia, "Standards Organizations". http://en.wikipedia.org/wiki/Standards_organization
[3] Ibid.
[4] See ISO, "Certification". http://www.iso.org/iso/home/standards/certification.htm
[5] ISO, "Certification". http://www.iso.org/iso/home/standards/certification.htm

3. Ethics assessment: Prevalence and Aims

The organisations analysed for the purposes of this report represent a patchwork of types and natures. Some of these are global (focus area), others are regional and some operate within national confines. The offerings of the analysed organisations include:

- Quality assurance for higher education
- Accreditation of educational courses
- Accreditation of organisations conducting clinical trials
- Accreditation of organisations using animals in research, teaching or testing.
- Online self-accreditation tool covering the basic requirements for undertaking primary care research
- Certification of quality and protections for human research
- Accreditation of audit research ethics committees (REC) administrative procedures
- Standards for social responsibility and managing ethical and social risk in the supply chain
- Certification of ethical behaviour/corporate social responsibility/responsible business practice, of ethics compliance programs and practices
- Risk assessment tools to manage ethical risk in supply chains
- Certification of professionals

4. Institutional set-up

Each of the analysed organisations has their own institutional structure, based on their size and what they offer. The well-established and larger organisations present more visible data about their corporate governance and institutional structures. This section outlines the institutional structures of the analysed organisations. First, it looks at standardisation organisations followed by certification and accreditation organisations (specifically relevant to SATORI).

4.1. Standards organisations

The **ISO (International Organization for Standardization)** is an independent, non-governmental membership organisation, developing voluntary international standards.[6] It is made up of 162 member countries represented by the national standards bodies around the world, with a Central Secretariat that is based in Geneva, Switzerland.[7] ISO has published more than 19,500 international Standards covering a wide range of sectors from technology, to food safety, to agriculture and healthcare.[8] The ISO's members meet once a year for a General Assembly that decides its strategic objectives. It has a Central Secretariat in Geneva, Switzerland, that coordinates the system. Operations at the Central Secretariat are directed by the Secretary General.

As highlighted before, at the EU level, CENELEC together with CEN, the European Committee for Standardization, and ETSI, the European Telecommunications Standards Institute are the European Standards Organizations (ESOs) that are officially recognised by the

[6] ISO, "About ISO". http://www.iso.org/iso/home/standards/certification.htm; ISO, "Structure and governance". http://www.iso.org/iso/home/about/about_governance.htm
[7] Ibid.
[8] ISO, "About ISO". http://www.iso.org/iso/home/standards/certification.htm; ISO, "Structure and governance". http://www.iso.org/iso/home/about/about_governance.htm

European Commission and act as a European platform through which European Standards are developed. In the case of CEN and CENELEC, "European standards are developed according to the principles of national delegation, whereby their members -the National Standards Bodies (NSBs) of the EU Member States[9] and the EFTA states - are responsible for developing European consensus".[10] The key players in the standards process are industry (as a direct member of the process in ETSI or through the national delegations in CEN and CENELEC; SME representation is reinforced by Small Business Standards (SBS), societal stakeholders (consumer, trade union and environmental bodies such as ANEC, ETUI and ECOS play important roles in European standardisation in representing consumer, trade union and environmental interests) and public authorities (who "drivers for standardisation through the development of standards-receptive legislation, the issue of standardisation mandates and public procurement. They provide significant funding to standardisation, both for the ESOs and the NSBs"). [11]

4.2. Certification and accreditation organisations (specifically relevant to SATORI)

The **World Certification Institute (WCI)** is a global certifying body that grants credential awards to individuals as well as accredits courses of organisations. It provides a structured assessment system to assess and certify globally accepted experiential work practices, skills, competencies and professional management. The basic criteria for receiving credential awards are adequate years of experience and demonstration of competence in a specific field of occupation.[12] Its professional activities are coordinated through authorised and accredited centres in America, Europe, Asia, Oceania and Africa.[13]

Sedex (which provides a risk assessment tool to manage ethical risk in the supply chain) is "dedicated to driving improvements in ethical and responsible business practices in global supply chains".[14] Sedex Information Exchange (Sedex) is a not-for-profit membership association, incorporated in the UK as a company limited by guarantee. It is a membership association that operates for the mutual benefit of all its members.[15] Sedex is headquartered in London with regional offices in Shanghai, China and New York, USA.[16]

Clinical Research Society (CRS), responsible for the Emerging Clinical Research Professional (ECRP) Certification, is a registered, non-profit, independent membership organisation. CRS states it "is the primary resource for clinical and translational medicine providing leadership for ethical and meaningful innovations that leads to betterment of mankind". It seeks to provide an interdisciplinary platform for professionals working in contract research, pharmaceutical, biotechnology and medical device industries, and those in hospital, medical research institutes and physician clinics. CRS is comprised of a community of more than 23,000 professionals in over 160 countries dedicated to drug/device development and healthcare. CRS was founded in 2006 to address the knowledge sharing need of interdisciplinary professionals in the pharma-biotech industry and, in particular, to develop a

[9] A list of NSBs is available at : http://standards.cen.eu/dyn/www/f?p=CENWEB:5
[10] European \Commission, "Standardisation - key players". http://ec.europa.eu/enterprise/policies/european-standards/key-players/index_en.htm
[11] Ibid.
[12] WCI, "About WCI". http://www.worldcertification.org/about-wci/
[13] Ibid.
[14] Sedex. http://www.sedexglobal.com/
[15] Sedex, "Corporate governance". http://www.sedexglobal.com/about-sedex/corporategovernance/
[16] Sedex. http://www.sedexglobal.com/about-sedex/corporategovernance/#sthash.KwMMQw2Y.dpuf

common understanding of the ethical principles, necessary for research on human subjects.[17] CRS has Council Members and representation from professionals from across the globe. Executive Council Members provide necessary guidance and support various initiatives of the Society.

AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) International is a private, non-profit organisation promoting the humane treatment of animals in science through voluntary accreditation and assessment programs.[18] AAALAC is governed by a Board of Trustees which comprises more than 60 scientific, educational and professional organisations (or member organisations). Each member organisation appoints a representative to serve a three-year term on the AAALAC Board. AAALAC suggests that "by actively involving major organisations, AAALAC International remains responsive to the issues that members face, while making sure that members of the scientific community understand and support the AAALAC International accreditation program".[19] The Council on Accreditation (at the centre of AAALAC's mission and work) comprises highly accomplished animal care and use professionals from around the globe who conduct the program assessments that determine which institutions are awarded AAALAC accreditation. Their responsibilities include conducting site visits, reviewing site visit reports, evaluating information, reviewing yearly reports from accredited institutions, and conferring the accreditation status of institutions. The Council is divided into North American, European, and Pacific-rim sections. AAALAC maintains a worldwide pool of more than 300 ad hoc consultants/specialists who have expertise beyond the realm of traditional laboratory animal species as well as specific expertise (for example, in aquatics, or agricultural science). Many also have unique discipline competencies, such as applied neuroscience, behavioural science, toxicology, pharmacology or physiology.

The **Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)** promotes high-quality research through an accreditation process[20] that helps organisations worldwide strengthen their human research protection programs (HRPPs). The AAHRP is an independent, non-profit accrediting body and uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. AAHRP's senior level staff provide strategic and substantive leadership and oversight on all aspects of AAHRPP's operations; assist organisations through all stages of the accreditation process, provide oversight of the review process and of educational programming for AAHRPP clients as well as the larger research community; undertake global business development and community relations. AAHRPP site visitors review applications and conduct their own comprehensive peer-review assessment, which includes an on-site evaluation.[21] AAHRPP's Board of Directors is responsible for overseeing the accreditation process. The Board is composed of individuals concerned with research involving humans as research participants. Five of AAHRPP's directors represent research participants or other community stakeholders.[22] AAHRPP's Council on Accreditation reviews applications and reports, and makes determinations regarding accreditation; it comprises of members appointed by the Board of Directors. Council members are experienced AAHRPP site visitors.[23]

[17] Clinical Research Society. http://www.clinicalresearchsociety.org/welcome-to-crs/
[18] AAALAC. http://www.aaalac.org/about/index.cfm
[19] AAALAC, "Accreditation FAQs". http://www.aaalac.org/accreditation/faq_landing.cfm#F2
[20] Any public or private (non-profit or for-profit) organisation that is located in or outside the United States and engaged in human research may be accredited.
[21] AAHRPP, "Site visitors". http://www.aahrpp.org/learn/about-aahrpp/site-visitors
[22] AAHRPP, "Board of Directors". http://www.aahrpp.org/learn/about-aahrpp/board-of-directors
[23] AAHRPP, "Council on Accreditation". http://www.aahrpp.org/learn/about-aahrpp/council-on-accreditation

The **Ethisphere® Institute** is a global organisation engaged in "defining and advancing the standards of ethical business practices that fuel corporate character, marketplace trust and business success".[24] Ethisphere began in 2007 as an online industry e-newsletter published by corporate compliance and ethics training and consulting firm, Corpedia. It evolved into a quarterly print Ethisphere Magazine publication with a large circulation of corporate, academic, legal and governmental subscribers.[25] It has a number of Advisory Boards.[26]

Social Accountability Accreditation Services (SAAS) is an accreditation agency that works to evaluate, accredit, and monitor organisations that demonstrate competency to audit and certify organisations that conform to social standards.[27] SAAS began work in 1997 as an accreditation department within Social Accountability International (SAI)[28] and was formally established as its own independent, not-for-profit organisation in 2007. SAAS has since expanded its scope to include accrediting bodies to audit against the InterAction PVO standard, conducting oversight of the BSCI verification code, development of the Magen Tzedek program, accreditation of the GoodWeave International system, and oversight and monitoring of the organisations delivering SA8000 Training.

The US-based **Compliance Certification Board (CCB)** develops criteria to determine competence in the practice of compliance and ethics across various industries and specialty areas, and recognizes individuals meeting these criteria through its compliance certification programs.[29] The Society of Corporate Compliance and Ethics and the Health Care Compliance Association (SCCE/HCCA) created an independent certification body called the Compliance Certification Board (CCB).[30] The CCB is an independent body made up of compliance and ethics professionals who determine what obligations needed to be fulfilled prior to and after certification, including Continuing Education Units (CEUs).[31] Early on, CCB hired Applied Measurement Professionals (AMP), a testing organisation that employs doctorate-level (PhD/EdD) psychometricians and statisticians to facilitate all phases of CCB's examination development process, including job analysis/validation, construction, administration, and scoring.

At the EU regional level, there is one organisation deals with quality assurance in higher education. The **European Association for Quality Assurance in Higher Education (ENQA)** is a membership association which represents its members at the European level and internationally. ENQA members are quality assurance organisations from the European Higher Education Area (EHEA) that operate in the field of higher education. The membership criteria of ENQA encompass Part III of the Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG)[32] and some additional requirements and guidelines. Bodies that do not wish to, or for whatever reason are unable to, apply to become members of

[24] Ethisphere. http://ethisphere.com/about/#sthash.1v5JUopV.dpuf
[25] http://ethisphere.com/about/history/#sthash.uIiVW7I8.dpuf
[26] Further details at: http://ethisphere.com/about/advisory-boards/#sthash.4kC2xFUM.dpuf
[27] SAAS. http://www.saasaccreditation.org/about
[28] Social Accountability International. http://www.sa-intl.org/
[29] http://www.compliancecertification.org/
[30] Snell, Roy, "Compliance certification by the profession, for the profession, and of the profession", Undated. http://www.compliancecertification.org/portals/2/PDF/CCB/ceo-letter-certification-facts.pdf
[31] Ibid.
[32] ENQA, *Standards and Guidelines for Quality Assurance in the European Higher Education Area*, European Association for Quality Assurance in Higher Education, 3rd Edition, Helsinki, 2009. http://www.enqa.eu/wp-content/uploads/2013/06/ESG_3edition-2.pdf

ENQA may request affiliate status within ENQA. Affiliates are bona fide organisations or agencies with a demonstrable interest in the quality assurance of higher education.[33] ENQA consists of three entities: General Assembly, Board and Secretariat. The General Assembly, composed of the representatives of the ENQA member agencies, with representatives of respective European Ministries and stakeholders attending as observers, is the main decision-making body of the association.[34]

This next part looks at institutional structures in other certification and accreditation organisations at the national level (public sector/regulated).

The **Central Committee on Research Involving Human Subjects (CCMO)** was established on the basis of section 14 of the Medical Research Involving Subjects Act (WMO). The CCMO was created in 1999 and is based in The Hague, the Netherlands[35]. The organisation and operation of the CCMO is laid down in its rules and regulations, which along with the complaints procedure, have been approved by the Minister of Health, Welfare and Sport (VWS). With regards to the organisation's operation, the CCMO has authorised its chair and/or executive director for certain (aspects of it's) jurisdictions. These are laid down in standing orders which approved by the Minister of Health, Welfare and Sport (the standing orders are only available in Dutch). The committee members of the CCMO are appointed by the minister on the basis of expertise. They carry out their work for the CCMO alongside their regular positions and also regularly offer expertise to other bodies. If a member has various roles and contacts it does not necessarily have to pose a problem for their activities for the CCMO. However, their interests, conflicting or not, must be transparent.[36]

The Medicines and Healthcare Products Regulatory Agency (MHRA) runs the MHRA phase I accreditation scheme - a voluntary scheme for organisations conducting phase I trials, in particular for those conducting first in human (FIH) trials).The MHRA is an executive agency, sponsored by the UK Department of Health.[37] It is the UK's regulator of medicines, medical devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness. It employs more than 1,200 people. The MHRA is governed by the agency board, who are advised by the corporate executive team (CET).[38]

The National Health Service (NHS) Health Research Authority (HRA) protects and promotes the interests of patients and the public in health research, streamlines the regulation of research and is responsible for a wide range of projects to streamline research, and provides Integrated Research Application System (IRAS) on behalf of the IRAS partners.[39] It is also responsible for Research Ethics Committees (RECs),[40] the Gene Therapy Advisory

[33] ENQA. "ENQA in a Nutshell". http://www.enqa.eu/index.php/about-enqa/enqa-in-a-nutshell/
[34] ENQA. http://www.enqa.eu/index.php/about-enqa/enqa-organisation/
[35] CCMO. http://www.ccmo.nl/en/ccmo
[36] CCMO. http://www.ccmo.nl/en/independance
[37] MHRA. https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
[38] MHRA, "Our governance". https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance
[39] HRA, "About the HRA". http://www.hra.nhs.uk/about-the-hra/
[40] HRA, "Research Ethics Committees". http://www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs/

Committee[41] and the Confidentiality Advisory Group (CAG),[42] which advises on Section 251 of the NHS Act (2006).[43]

Pharmacy Research UK (which developed the Research Ready online self-accreditation tool), is a research charity supporting pharmacists and pharmacy to improve healthcare for the benefit of patients and the public. It was founded in 2012, out of a merger between the Pharmacy Practice Research Trust (PPRT) and the Pharmaceutical Trust for Educational and Charitable Objects (PTECO) to bring about improved efficiency and use of funds to current and future beneficiaries, with the ultimate aim of providing the best possible assistance to those who benefit from its work.[44] The Scientific Advisory Panel was established: to advise the Board of Trustees on the development of Pharmacy Research UK's research grant giving strategy and policies and to review the strategy as appropriate; to ensure independent review of proposals for research funding and make recommendations to the Trustees for allocation of research funds and to oversee processes for timely monitoring and reporting of funded research activity.[45]

The **Quality Assurance Agency for Higher Education (QAA)** is the independent body entrusted with monitoring and advising on standards and quality in UK higher education. The QAA is a registered charity and a company limited by guarantee and is funded through a number of channels:[46]

- subscriptions from higher education providers (all publicly funded higher education providers in the UK subscribe to QAA and pay an annual fee, as do some that are not publicly funded)
- contracts and agreements with the UK funding councils and organisations to which QAA reports annually
- providers of higher education seeking educational oversight for immigration purposes as required by the Home Office pay a fee to be reviewed by a QAA team, as well an annual maintenance charge
- contracts with the General Osteopathic Council (GOsC), and with the National College for Teaching and Leadership for Early Years Professional Status (EYPS)

[41] HRA, "Gene Therapy Advisory Committee (GTAC)". http://www.hra.nhs.uk/about-the-hra/our-committees/gtac/

[42] CAG provides independent expert advice to the HRA (for research applications) and the Secretary of State for Health (for non-research applications) on whether applications to access patient information without consent should or should not be approved. The role of CAG is to review applications and advise whether there is sufficient justification to access the requested confidential patient information. Using CAG advice as a basis for their consideration, the HRA or Secretary of State will take the final approval decision. See http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/

[43] Section 251 came about because it was recognised that there were essential activities of the NHS, and important medical research, that required the use of identifiable patient information – but, because patient consent had not been obtained to use people's personal and confidential information for these other purposes, there was no secure basis in law for these uses. Section 251 was established to enable the common law duty of confidentiality to be overridden to enable disclosure of confidential patient information for medical purposes, where it was not possible to use anonymised information and where seeking consent was not practical, having regard to the cost and technology available. See: http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/what-is-section-251/#sthash.OxVgdEQu.dpuf

[44] Pharmacy Research UK, "Our story". http://www.pharmacyresearchuk.org/about-us/our-story/

[45] Pharmacy Research UK, "Scientific Advisory Panel". http://www.pharmacyresearchuk.org/about-us/our-scientific-advisory-panel/

[46] QAA, "Corporate Governance. Our Structure and funding". http://www.qaa.ac.uk/about-us/corporate-governance

- additional private contracts, consultancy and business development work in the UK and internationally.[47]

The **Ethical Company Organisation** is a small, limited company based in the UK, entirely funded through the sale of its research and publications (for individuals, ethical businesses and campaigning NGOs), research fees relating to its ethical accreditation scheme and through highly screened sponsorship/advertising in its publications.[48]

5. Ethical values, principles and issues

This section highlights the ethical values, principles as aspects underlying the standards, certification and accreditation offered by the analysed organisations.

The table below illustrates the basis of the standard, certification or accreditation offered, the ethical values and principles addressed (non-exhaustively listed[49]) and other aspects if relevant. The organisations are listed alphabetically.

Organisation	Basis/Criteria	Ethical values, principles	Other aspects
AAALAC International accreditation program	**Three Primary Standards** for evaluating laboratory animal care and use programs[50]	These include scientific, humane, and ethical principles. Humane care and use of laboratory animals. The Three Rs (replacement, refinement, and reduction) Oversight.	
AAHRPP accreditation	AAHRPP Accreditation Standards	Ethical principles and standards appropriate for discipline. Oversight. Disclosure, elimination of financial conflicts of interest. Sound study design Minimisation of risks to participants. Determination of resources necessary to protect participants. Fair and equitable recruitment of participants. Use of consent processes and methods of documentation. Compliance with all applicable laws, regulations, codes, and guidance.	
Central Committee on Research Involving Human	CCMO normative framework for medical-ethical	None are directly prescribed, but the framework refers to the regulations on Medical Research Involving Human Subjects Act (WMO), which prescribe how	Composition and procedures of committee

[47] Ibid.
[48] The Ethical Company Organisation, "About us". http://ethical-company-organisation.org/about-us/
[49] Please refer to the original documents for a more comprehensive picture.
[50] These are: the eighth edition of the NRC, *Guide for the Care and Use of Laboratory Animals*, Eighth Edition, The National Academies Press, Washington, 2011; Federation of Animal Science Societies, *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, Third Edition, January 2010; Council of Europe, European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Strasbourg, 18 March 1986 (ETS 123); other widely accepted guidelines.

Organisation	Basis/Criteria	Ethical values, principles	Other aspects
Subjects (CCMO) accreditation of MRECs	ethics committees	such research should or should not involve human subjects.	
ECRP Certification	The Certification and Training Program requirements	Ethics in Drug Development. Compliance with responsibilities for adverse event reporting.	
ENQA	Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG)	Quality and standards of higher education need to be safeguarded. Transparency and the use of external expertise in quality assurance processes. Processes should be developed through which higher education institutions can demonstrate their accountability, including accountability for the investment of public and private money. Quality assurance for accountability purposes should be fully compatible with quality assurance for enhancement purposes. Processes used should not stifle diversity and innovation.	
Ethisphere's Ethics Inside® Certified *seal*	100 separate criteria.	Ethical business practices.	
ISO	ISO 26000:2010	Social responsibility. Sustainable development. Compliance with law. Societal, environmental, legal, cultural, political and organisational diversity etc.	
MHRA accreditation	MHRA Phase I accreditation scheme requirements	Human safety	
NHS Health Research Authority Accreditation Scheme for Research Ethics Committees (RECs)	HRA Standard Operating Procedures and Governance Arrangements for Research Ethics Committees (GAfREC)	Dignity, rights, safety and well-being of research participants. Informed consent. The appropriate use and protection of patie nt data. Respect for the diversity of human society and conditions and the multi-cultural nature of society.	Performance and quality control.
QAA	UK Quality Code for Higher Education	Not clear. Maybe evident in subject benchmarks.	The Quality Code is grouped into three Parts: Part A on academic standards Part B on

Organisation	Basis/Criteria	Ethical values, principles	Other aspects
			academic quality Part C on information about higher education provision
Research Ready	The basic requirements for undertaking primary care research in the UK/ aligned with the Research Governance Frameworks	Dignity, rights, safety and well-being of participants. Informed consent. Due care. Appropriate use and protection of patient da ta confidentiality of personal information. Respect the diversity of human society and conditions and the multi-cultural nature of society. Keeping risks, pain or discomfort to a minimum. Three Rs for animal research. Quality of research, adequate review. Principles of Good Clinical Practice. Free access to information, health and safety. Respect for key elements of a quality research culture: respect for participants' dignity, rights, safety and wellbeing; valuing the diversity within society; personal and scientific integrity; leadership; honesty; accountability; openness; clear and supportive management.	
Sedex	As prescribed in the Risk Assessment Tool	Ethical and responsible business practices.	
Social Accountability 8000 International Standard (underlying SAAS accreditation)	Based on the UN Declaration of Human Rights, conventions of the ILO, UN and national law, and spans industry and corporate codes	Human rights. UN Guiding Principles on Business and Human Rights.	
The Bright Ethics Accreditation	No info on website	Ethical business	Environmenta l strategy, human resources, supply chain and procurement and tax arrangements.

Organisation	Basis/Criteria	Ethical values, principles	Other aspects
The Certified Compliance & Ethics Professional (CCEP)	Relevant regulations in compliance processes	Professionalism, integrity and competence. Compliance with the spirit and the letter of the law. High sense of integrity. Unprejudiced and unbiased judgment. Upholding dignity of the profession.	
The Ethical Company	Covers a very wide range of ethical criteria including animal welfare, human rights and the environment.	Animal rights. Environment. Human rights.	
World Certification Institute (WCI)	WCI criteria and code of ethical practices	Four core values: integrity in decisions and actions, competency in skills and professions, value in our economic contributions to employers & responsibility in social contributions to Society.[51]	Detailed examination of course content & duration; qualifications & competence of trainers; financial strength & integrity of course providers; available facilities & resources; method of delivery & assessment; and importantly their relevance to occupational & career development.

Table 1: Organisations, criteria and ethical values and principles

6. Procedures and tools

The following table summarises the applicable procedures and tools used. These procedures and tools are relevant to understand the variant natures and types, similarities, and established measures and also to increase our knowledge of good practices. This is particularly relevant to Work Package 7 of SATORI (Standardising Operating Procedures and Certification for Ethics Assessment), and provides an initial basis for the research that will be conducted in that Work Package. The organisations are listed alphabetically.

[51] See WCI, "Code of Ethical Practices". http://www.worldcertification.org/about-wci/code-of-ethical-practices/

Organisation	Procedures/tools
AAALAC International accreditation program	The accreditation process includes an extensive *internal* review conducted by the institution applying for accreditation.[52] During this review, the institution creates a comprehensive document called a "Program Description" which describes all aspects of the animal care and use program (policies, animal housing and management, veterinary care, and facilities). The Program Description is then submitted to AAALAC. Next, AAALAC evaluators (members of AAALAC's Council on Accreditation) review the Program Description and conduct their own comprehensive on-site assessment. The site visitors' report is then reviewed by the entire Council on Accreditation and accreditation status is determined. If deficiencies are found, they are outlined in a letter and the institution is given a period of time to correct them. Once the deficiencies are corrected, accreditation is awarded. The entire process is *completely confidential.* After an institution earns accreditation, it must be re-evaluated every three years in order to maintain its accredited status. Currently more than 900 organisations in 39 countries have earned AAALAC accreditation.
AAHRPP accreditation	AAHRPP accreditation steps: self-assessment to identify and remedy program weaknesses; review/consideration of application; site visit, onsite evaluation; review of application by the Council on Accreditation; drafting of site visit report; the organisation's response, and the evaluation of the response. At its quarterly meeting, the Council then makes a determination regarding accreditation. Decision of the Council is communicated to the organisation in writing. AAHRPP issues a Certificate of Accreditation to each organisation that receives Full Accreditation or Qualified Accreditation. The initial accreditation period is three years. Thereafter, the accreditation period is five years. Failure to submit renewal applications by the deadline could result in a loss of accreditation status.
Central Committee on Research Involving Human Subjects (CCMO) accreditation of MRECs	The CCMO checks whether an accredited medical ethical reviewing committee (MREC) meets obligations (accreditation) and oversees their operations. The CCMO can set up new guidelines with regards to the operations of accredited MRECs.[53] The criteria for accreditation are laid down in the Medical Research Involving Human Subjects Act (WMO). A research ethics committee has to fulfil the minimal composition, has to have standing orders and SOPs in which their operations are described and has to review on average 10 research protocols per year or more. If an MREC no longer fulfils the criteria, the accreditation can be withdrawn.
ECRP Certification	The ECRP Certification program is a structured program that delivers core trainings in all basic areas of drug development and clinical research. This study module that comprises of multiple lectures and presentations introduces the individual to the pharmaceutical and clinical research industry. CRS has partnered with ProctorU to offer proctored exams for all Certification

[52] AAALAC, "Accreditation". http://www.aaalac.org/accreditation/
[53] CCMO, "Tasks of the CCMO". http://www.ccmo.nl/en/tasks-of-the-ccmo

Organisation	Procedures/tools
	Programs. The ECRP certification is valid as long as the Student/Associate membership stays active.[54]
ENQA	In order to become a member of ENQA, QA agencies are required to successfully undergo an external review and thereby to show that they comply sufficiently with the ESG. External reviews are based on the following principles:[55] • the review is an **evidence-based process** carried out by independent experts; • the information provided by the agency is assumed to be **factually correct** unless other evidence points to the contrary; • the review is a **process of verification** of the information provided in the self-evaluation report and other documentation and the exploration of any matters which are omitted from that documentation; • the level of conformity with the ENQA membership criteria (and thereby, the ESG) that is expected is "**substantial compliance**", not rigid adherence; • the second and subsequent rounds of reviews aim at striving for **improvement**. ENQA coordinates all reviews in order to guarantee a higher level of homogeneity of the reviews. Nationally coordinated reviews are still possible in cases where agencies are subjected to national reviews due to national regulations.
Ethisphere's Ethics Inside® Certified *seal*	Ethisphere Institute analysts look at more than 100 separate criteria. All applicants are provided with detailed reports as to how their programs measure up – including suggestions and guidelines for improvement. Companies that pass the certification criteria are provided with the award and license to use the "Ethics Inside® Certified" logo in corporate communications and promotion.[56]
ISO	An ISO standard is developed by a panel of experts, within a technical committee.[57] Once the need for a standard has been established, these experts meet to discuss and negotiate a draft standard. As soon as a draft has been developed it is shared with ISO's members who are asked to comment and vote on it. If a consensus is reached the draft becomes an ISO standard, if not, it goes back to the technical committee for further edits.
MHRA Phase I accreditation	Potential applicants submit a completed application form (available from the MHRA website) and any associated documents to the MHRA Good Clinical Practice (GCP) inspectorate. This is assessed and on completion of a successful inspection verifying that all the requirements have been met, the unit is recommended for accreditation. A unit must be able to demonstrate that it is able to carry out clinical trials with compounds at all levels of risk, including those that have never been tested in man (FIH) and those that require review of risk factors by the EAG. This means they

[54] Clinical Research Society, "Emerging Clinical Research Professional (ECRP) Certification. http://www.clinicalresearchsociety.org/ecrp/
[55] ENQA, "Principles of external reviews". http://www.enqa.eu/index.php/reviews/principles-of-external-reviews/
[56] Ethisphere, "Ethics Inside Certified". http://ethisphere.com/services/ethics-inside-certified/#sthash.0gl2yhpI.dpuf
[57] ISO, "How does ISO develop standards". http://www.iso.org/iso/home/standards_development.htm

Organisation	Procedures/tools
	must have formal procedures in place and appropriately trained and experienced staff available to cover all the requirements stated in Appendix 1 of the PHASE I Accreditation Scheme Requirements Guidance document.[58]
NHS Health Research Authority Accreditation Scheme for Research Ethics Committees (RECs)	These are set out in HRA Standard Operating Procedures and Governance Arrangements for Research Ethics Committees (GAfREC). RECs are issued with an audit decision – full accreditation, accreditation with conditions (low risk non-compliance identified requiring an action plan) and provisional accreditation (high and low risk issues requiring an action plan).[59]
QAA	The Quality Code is the core reference point used in all review activity. QAA reviews how providers of higher education, such as universities and colleges, maintain their academic standards and quality, and reports on findings.
Research Ready self-accreditation	Research Ready is a streamlined web based self-assessment tool.[60] Applicants are required to complete an initial registration and will then be sent login details to complete the accreditation process. Applicants must be able to answer 'yes' to all the questions in the assessment and enter information on their practice demographics and research interests. Applicants choose whether they wish to be accredited to a level that supports the undertaking of clinical trials. Applicants are expected to download a copy of the Core Competency Demonstration form from the accreditation site and maintain this as evidence of how they meet the criteria. Following completion of the accreditation questionnaire an administration charge of £150 is levied to cover a three year period of accreditation. This charge is non-profit making and covers the back office costs required to run the Research Ready programme.
SAAS accreditation to SA8000	SAAS undertakes a verification process to assess the CB's competence through a series of audits which reviews the management, processes, and auditor qualifications of the CBs certification process. The CB, in turn, evaluates the implementation of the accredited social system at a factory, farm or other organisation to ensure compliance with all elements of the system. Once a Certification Body is granted accreditation by SAAS, the Certification Body is able to certify facilities that comply with SA8000 and other social standards within SAAS's scope of accreditation.[61]
Sedex risk assessment tool	The Risk Assessment Tool includes the following features: • Reporting tool • Pre-screening tool • Risk scorecard • Benchmarking tool The risk score is calculated using inherent risk (based on country, product area, sector profile and site function) and management proficiency risk (based on data from the Self-Assessment

[58] MHRA, "MHRA Phase I Accreditation Scheme Requirements", Version 2, 31 October 2013. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/262606/Phase_I_Accreditation_Scheme_requirements.pdf
[59] HRA, "Quality assurance". http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/#sthash.E0K1HaNm.dpuf
[60] RCGP, "Research Ready". http://www.rcgp.org.uk/researchready
[61] SAAS, "Accreditation process". http://www.saasaccreditation.org/accreditation-process

Organisation	Procedures/tools
	Questionnaire). The combined overall risk is based on a combination of these two scores. The Risk Assessment Tool draws on Maplecroft intelligence to deliver in-depth analysis. This intelligence covers hundreds of risk indices, using thousands of indicators. Maplecroft keeps abreast of the latest risk issues and this knowledge is fed back into the Risk Assessment Tool on a regular basis, ensuring that you have the most up to date risk scores.
The Bright Ethics Accreditation	Applicants to contact Bright Ethics. Companies are audited around four key areas: Environmental Strategy, Human Resource Practice, Supply Chain, Procurement and Tax Arrangements.
The Certified Compliance & Ethics Professional (CCEP)	Individuals who meet eligibility requirements and who successfully pass the examination attain the two-year CCEP designation. Steps: 1. Gain work experience, 2. Earn and submit the required Continuing Education Units (CEUs), 3. Apply to take the exam, 4. Schedule the exam, 5. Take the exam.
The Ethical Company Organisation accreditation	The application process takes 6 weeks and involves research teams analysing each applicant company's record on up to 15 specific criteria under the three general headings of Environment, Animals and People. The Ethical Company searches for criticisms within several thousand documents from NGO'S, campaign groups and court reports. *Ethical Accreditation* screening includes the applicant company and its ultimate holding company. The research is repeated every 12 months to ensure that *Ethical Accreditation* awards remain up to date.[62] All Ethical Accreditation licence awards are annual and automatically renew every year, subject to certain safeguards and a successful review by the Ethical Company Organisation.
World Certification Institute (WCI)	Those applying for a Certified Credential Award; namely WCP, WCSP, or WCMP must possess the required qualifications from WCI accredited organisations**.** WCI accredits courses conducted by organisations that are not in the listing of WCI accredited organisations. These organisations could be colleges, schools, training companies, professional institutions, and universities. The process of accrediting courses conducted by non-WCI accredited organisations is more rigorous for new course providers. This process entails detailed examination of course content & duration; qualifications & competence of trainers; financial strength & integrity of course providers; available facilities & resources; method of delivery & assessment; and importantly their relevance to occupational & career development. Only WCI Councillors or WCI-appointed Committees of Experts can accredit courses. When a course is successfully accredited, graduates of the accredited course will meet the qualification criteria for WCI Certified Credential Awards. An organisation that has its courses successfully accredited will receive a Certificate of Accreditation from WCI that lists the courses accredited and the eligibility level of the Certified Credential Award. The organisation can also print on its award certificate with the words "Course Accredited by World Certification Institute", alongside WCI logo. Organisations

[62] The Ethical Company Organisation, "Apply for ethical accreditation". http://ethical-company-organisation.org/accreditation/apply-for-ethical-accreditation/

Organisation	Procedures/tools
	applying for accreditation of their courses by WCI are required to furnish their information in a prescribed form.[63]

Table 2: Applicable procedures and tools

7. Developments

We must also recognise privacy standards and certification efforts by various organisations. Privacy is both an ethical principle and a fundamental right. Privacy standards and certification efforts are well-established, and the use of privacy impact assessment methodologies is growing. The experience of developing privacy standards and certification initiatives could provide, or could be used to derive some learnings for developing a certification framework for SATORI in WP7.

ISO/IEC 29100:2011 *Information technology -- Security techniques -- Privacy framework*:

- provides a privacy framework which: specifies a common privacy terminology;
- defines the actors and their roles in processing personally identifiable information (PII);
- describes privacy safeguarding considerations; and
- provides references to known privacy principles for information technology.[64]

ISO/IEC 29100:2011 is applicable to natural persons and organisations involved in specifying, procuring, architecting, designing, developing, testing, maintaining, administering, and operating information and communication technology systems or services where privacy controls are required for the processing of PII. Another relevant ISO standards is ISO/IEC 27018:2014 which establishes commonly accepted control objectives, controls and guidelines for implementing measures to protect Personally Identifiable Information (PII) in accordance with the privacy principles in ISO/IEC 29100 for the public cloud computing environment.[65] ISO also has *ISO/IEC WD 29134 Privacy impact assessment - Methodology* under development.[66]

There are also a number of privacy certification organisations that provide privacy certification services. A point of note is that even some data protection authorities offer (and are considering) data protection certification – e.g. the Unabhängiges Landeszentrum für Datenschutz Schleswig-Holstein (ULD),[67] CNIL (France)[68] and the UK ICO.[69] The EU Privacy Seals project inventoried and analysed existing privacy certification schemes.[70] It identified and analysed the scientific and organisational success factors for an EU privacy certification scheme; assessed the scope and rules of such a scheme and the roles of the various public and private stakeholders in its development, and its relationship to existing legislation and the proposed General Data Protection Regulation (GDPR). The Study started in April 2013 and

[63] WCI, "Accreditation of courses". http://www.worldcertification.org/accreditation-of-courses/
[64] ISO, ISO/IEC 29100:2011 *Information technology -- Security techniques -- Privacy framework.* http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=45123
[65] ISO. http://www.iso.org/iso/catalogue_detail?csnumber=61498. There are also other ISO privacy related standards relevant to mobiles, RFID.
[66] ISO. http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=62289
[67] https://www.datenschutzzentrum.de/audit/
[68] http://www.cnil.fr/linstitution/labels-cnil/
[69] https://iconewsblog.wordpress.com/2015/01/28/what-you-need-to-know-about-ico-privacy-seals/
[70] Deliverables are available in the EU Bookshop. https://bookshop.europa.eu/en/home/

concluded in July 2014. The findings and results of this Study (documented in the EU Bookshop) might be relevant to draw some lessons for SATORI.

8. Discussion

There are many benefits (perceived and actual) of standards, certification and accreditation provided by the organisations we have analysed. However, they vary. They also depend on the nature of the standard, certification or accreditation, its underlying criteria and at whom it is targeted.

Standards not only create benchmarks for the sector or organisations that they apply to or subscribe to them, but can be used to gain greater trust and credibility. They can have a direct and beneficial impact on society. Standards such as the ISO 26000 provide guidance to businesses and organisations as to how they can operate in a socially responsible manner. It also facilitates their actual actions to meet this objective ultimately contributing to positive societal outcomes.

Certification provides organisations a means of determining (whether through self- or third party certification) whether and to what extent they comply with ethical standards, rules and regulations (depending on what the criteria are). This creates compliance and reputational advantages. Ethisphere (which issues the Ethics Inside® Certified seal) suggests that its certification has the potential to attract business, talent and investment to certified entities, and helps demonstrate that an organisation is making a real effort to prevent compliance failures.[71] In some cases, as reported by the AAHRPP, it even "provides an excellent return on their investment".[72]

The SAAS cites the following benefits of accreditation:[73]

> Certification bodies need to be accredited to assure stakeholders that these companies are able to consistently and reliably perform a certification audit and that these audits are carried out in a professional manner. Accreditation provides independence that contributes to impartial assessments of all bodies within the system. The purpose of accreditation is to assure that auditing bodies are competent to do the work they undertake and that their audit practices are undertaken impartially, competently and effectively, reducing risk to the system. Owners of social and environmental audit systems need to ensure that the audit system meets its intended purpose and that third party validation is performed by audit companies qualified to do so. Accreditation provides validation that the system fulfils its intended requirements.

So how successful are these standards, certification and accreditation organisations? We try to determine this with the help of some statistics

The AAHRPP reports "it has accredited organisations in 46 states, Canada, China, India, Mexico, Republic of Korea, Saudi Arabia, Singapore, Taiwan, and Thailand. All major U.S. independent institutional review boards have earned AAHRPP accreditation. In addition, more

[71] Ethisphere, "Ethics Inside Certified". http://ethisphere.com/services/ethics-inside-certified/
[72] AAHRPP, "Value of accreditation". http://www.aahrpp.org/learn/considering-accreditation/value-of-accreditation
[73] SAAS, "The value of accreditation". http://www.saasaccreditation.org/value-of-accreditation

than 60 percent of U.S. research-intensive universities and over 65 percent of U.S. medical schools are either AAHRPP accredited or have begun the accreditation process."[74]

There are 24 accredited MRECs in the Netherlands that review medical/scientific research proposals. The majority are linked to an institution such as an academic medical centre or a hospital.[75] As of 22 December 2014, there are 15 MHRA Accredited Phase I Units in the UK.[76] Summary statistics show there are 166 Research Ready accredited pharmacies in England, Scotland and Wales.[77] A Royal College of General Practitioners (RCGP) Press Office release states, "Around one in eight GP practices across the UK are now 'Research Ready', after signing up to an initiative by the Royal College of General Practitioners (RCGP) to encourage GP teams and patients to get involved in primary care research. 1006 GP practices have now completed the online self-assessment designed to ensure that practices are aware of their responsibilities to both themselves and their patients when they get involved in research".[78]

The SAAS website lists 23 Certification Bodies accredited to deliver SA8000 audits and certificates of compliance to the SA8000 Standard. [79]

CCB reports that "More than 7,800 people actively hold at least one of the following compliance and ethics professional certifications, including an international certification for individuals who work outside the United States or those who have international affiliates".[80]

AAALAC reports that "more than 900 organizations in 39 countries have earned AAALAC accreditation".[81] However, note that analysis conducted by People for the Ethical Treatment of Animals (PETA) has found that laboratories accredited by AAALAC violate national animal welfare guidelines more frequently than do unaccredited facilities.[82] AAALAC rebuts this saying that: The underlying assumptions about the nature of the data analysed are significantly flawed and thus cannot support the authors' conclusions; The data do not reflect on the quality outcomes for the *majority* of animals used in research, testing and teaching (90 % of which are laboratory rats, mice and ectotherms) which are covered to great benefit during reviews in AAALAC International accredited institutions, but are not overseen by the USDA inspections; and that the authors' motives and conclusions clearly reflect their ideological slant against the use of animals in research.[83]

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[74] AAHRPP, "Seven More Research Organizations Earn AAHRPP Accreditation, Including First in Thailand", *Press Release,* 19 December 2014. https://admin.share.aahrpp.org/Website%20Documents/4th%20quarter%202014%20accreditation%20release%20v3.pdf

[75] CCMO, "Accredited MRECs". http://www.ccmo.nl/en/accredited-mrecs

[76] MHRA, "List of Accredited Units". https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/391471/List_of_accredited_units__22_Dec_14_.pdf

[77] The Royal Pharmaceutical Society, "Research ready Pharmacies". http://www.rpharms.com/research-ready/research-ready-pharmacies.asp [Last update 11 February 2015]

[78] Royal College of General Practitioners (RCGP), "More than 1000 GP practices now 'Research Ready'", 27 January 2014. http://www.rcgp.org.uk/news/2014/january/more-than-1000-gp-practices-now-research-ready.aspx

[79] SAAS. http://www.saasaccreditation.org/accredcertbodies

[80] CCB, "Compliance Certification Board (CCB)". http://www.compliancecertification.org/

[81] AAALAC. http://www.aaalac.org/accreditation/index.cfm

[82] Grimm, David, "Animal welfare accreditation called into question", *Science*, Vol. 345 no. 6200, 29 August 2014, p. 988. http://www.sciencemag.org/content/345/6200/988

[83] AAALAC, "A note from AAALAC International regarding the recent article in Science Daily News", 28 August 2014. http://www.aaalac.org/news/index.cfm

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4. Central Committee on Research Involving Human Subjects (CCMO). http://www.ccmo.nl/en/ccmo
5. Clinical Research Society. http://www.clinicalresearchsociety.org/
6. Compliance Certification Board (CCB). http://www.compliancecertification.org/
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17. ISO. http://www.iso.org/
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27. Social Accountability International. http://www.sa-intl.org/
28. The Ethical Company Organisation. http://ethical-company-organisation.org/
29. The Royal Pharmaceutical Society, "Research ready Pharmacies". http://www.rpharms.com/research-ready/research-ready-pharmacies.asp
30. Unabhängiges Landeszentrum für Datenschutz Schleswig-Holstein (ULD). https://www.datenschutzzentrum.de/audit/
31. Wikipedia, "Standards Organizations". http://en.wikipedia.org/wiki/Standards_organization
32. World Certification Institute (WCI). http://www.worldcertification.org/

10. Annex

This section lists the organisations (and initiatives) considered in this study.

1. **Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International accreditation program** evaluates organisations that use animals in research, teaching or testing. Those that meet or exceed AAALAC standards are awarded accreditation. http://www.aaalac.org/accreditation/index.cfm
2. **Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accreditation** indicates that an organisation follows rigorous standards for ethics, quality, and protections for human research: http://www.aahrpp.org/http://docr.som.duke.edu/aahrpp-accreditation
3. **Central Committee on Research Involving Human Subjects (CCMO) accreditation** of MRECs in the Netherlands. http://www.ccmo.nl/en/accredited-mrecs
4. **Clinical Research Society's Emerging Clinical Research Professional (ECRP) Certification** (a training and certification program) aims to provide the individual with a robust understanding of the clinical research industry, historical perspective of drug development, basic concepts and methodologies in research, ethics in human research, and many other relevant topics. http://www.clinicalresearchsociety.org/ecrp/
5. **Compliance Certification Board (CCB) Certified Compliance & Ethics Professional (CCEP)®** is someone with knowledge of relevant regulations and expertise in compliance processes sufficient to assist organisations with their legal obligations, and someone who promotes organisational integrity through the operation of effective compliance programs. http://www.compliancecertification.org/CCEP/CertifiedComplianceEthicsProfessional.aspx
6. **Ethics Inside® Certified *seal*** is an independent verification of a company's ethics and compliance program and practices. The certification is exclusively awarded to companies that can demonstrably prove a superior employee and leadership culture that promote ethical business practices and have adequate compliance systems and programs to reasonably prevent compliance failures. http://ethisphere.com/certifications/ethics-inside-certified/
7. **European Association for Quality Assurance in Higher Education (ENQA),** an umbrella organisation which represents quality assurance organisations from the European Higher Education Area (EHEA) member states, promotes European co-operation in the field of quality assurance in higher education and disseminates information and expertise among its members and towards stakeholders in order to develop and share good practice and to foster the European dimension of quality assurance. http://www.enqa.eu/
8. **International Organization for Standardization (ISO)'s 26000:2010** provides guidance on how businesses and organisations can operate in a socially responsible way. ISO 26000:2010 provides guidance rather than requirements, so it cannot be certified to unlike some other well-known ISO standards. http://www.iso.org/iso/home/standards/iso26000.htm
9. **Medicines and Healthcare Products Regulatory Agency,** MHRA phase I **accreditation scheme** is a voluntary scheme for organisations conducting phase I trials, in particular for those conducting first in human (FIH) trials in the UK. The scheme aims to make sure trials are as safe as possible and to create public confidence in the regulation of phase I clinical trials. https://www.gov.uk/mhra-phase-i-accreditation-scheme
10. **NHS Health Research Authority Accreditation Scheme for Research Ethics Committees (RECs)** established, in 2007, a three year rolling accreditation programme in

order to audit REC administrative procedures to agreed administrative standards (UK). http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/#sthash.CkHeX8GY.dpuf

11. **Quality Assurance Agency for Higher Education (QAA):** the independent body entrusted with monitoring and advising on standardsand quality in UK higher education. http://www.qaa.ac.uk/about-us
12. **Research Ready** is an online self-accreditation tool covering the basic requirements for undertaking primary care research in the UK. Developed by Pharmacy Research UK **i**n conjunction with the Royal College of General Practitioners and the National Institute for Health Research Clinical Research Network, it is aligned with the Research Governance Frameworks in the UK. http://www.rpharms.com/research-ready/research-ready-online-assessment.asp
13. **Sedex** (a not-for-profit membership organisation dedicated to driving improvements in ethical and responsible business practices in global supply chains) has a Sedex **Risk Assessment Tool** to help manage ethical risk in the supply chain. http://www.sedexglobal.com/about-sedex/
14. **Social Accountability Accreditation Services (SAAS)** is an accreditation agency that works to evaluate, accredit, and monitor organisations that demonstrate competency to audit and certify organisations that conform to social standards. http://www.saasaccreditation.org/about
15. **The Bright Ethics Accreditation** recognises when companies act in an ethical way. It audits companies to see how ethical they are and offers solutions for improvement. Once a company has reached basic standards they can carry the Bright Ethics Mark on their packaging, promotion and website. Bright Ethics audits companies around four key areas: environmental strategy, human resources, supply chain and procurement and tax arrangements. http://www.brightethics.com/
16. **The Ethical Company Organisation** is the UK's only cross-spectrum (people, animals and environment) ethical accreditation, which exists to reward ethical companies' behavior. Companies with excellent scores according to an Ethical Company Index analysis may display its CSR standard marks and ethical ranking tables which provide up-to-date positive comparison with less ethical competition. http://ethical-company-organisation.org/
17. **World Certification Institute (WCI)** is a global certifying body that grants credential awards to individuals and accredits courses of organisations. It has a Code of Ethical practices. http://www.worldcertification.org/about-wci/code-of-ethical-practices/