EUROPEAN REGULATION AND INNOVATION FORUM – COMMUNICATION 20

PRINCIPLES AND GUIDELINES FOR SCIENTIFIC INTEGRITY IN REGULATORY STUDIES

("THE BERRY PRINCIPLES")

April 2021

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FOREWORD

We are deeply indebted to Sir Colin Berry for this important and timely communication on scientific integrity in regulatory decision-making.

The extraordinary value of what science can achieve, but also the importance of sustaining public confidence in what science can say, has been amply demonstrated by the on-going pandemic. This is not only a matter of laboratories and scientific committees; it is part of our everyday life.

Sir Colin proposes principles and guidelines for scientific integrity in four key areas of wide application. We are sure that they will be found to be of great value by practitioners, policy-makers and all those impacted by regulatory decisions. The European Regulation and Innovation Forum (ERIF) expresses it great appreciation for the opportunity to be associated with this work.

Howard Chase
Chairman
European Regulation and Innovation Forum
April 2021

INTRODUCTION BY SIR COLIN BERRY

The current pandemic has made clear that the mantra “follow the science” can be as dangerous as any platitude when applied indiscriminately. The triumphant demonstration of the value of research into fundamental processes of cellular replication and protein production has allowed the production of vaccines dependent on a profound understanding of how the mechanisms that surround the action of RNA in cells operate, on the use of vector viruses to introduce RNA into cells and on the ability to construct lipid encapsulation of RNA to allow it to maintain stearic integrity. All depend on profound understanding of cellar activities.

Less impressive are trials where dose regimes have not been followed, where participant selection has been sub-optimal, where protocols have not been adhered to, and where premature announcements of results have muddied the water. Assertions based on inadequate epidemiological data, subsequently found to be flawed, have been acted upon with consequences that have been damaging. Assertions about efficacy that are unfounded have damaged public confidence. It might well be argued that shortcomings are inevitable in exceptional times - this is clearly true, and their recognition has led to rapid changes in the care of those severely affected by COVID 19. Nevertheless, a failure to use “science” or rather, the scientific method, has sometimes impeded the route to a better management of events.

Current concerns about cerebral venous thrombosis in those given a particular vaccine illustrate difficulties of what might be called “result anticipation”. A consumptive coagulopathy appears to be associated with the administration of the AstraZeneca vaccine. That problem that presents to analyse is whether to attribute causation to a clinical event occurring at a low-frequency with other known (and unknown) causes – cerebral venous thromboses occur with the contraceptive pill, as a rare reaction to some given heparin and without any apparent cause. Firmly identifying an incremental change in a rare event, establishing temporal relationships to immunisation and excluding possible direct effects of the virus in those affected, needs studies that are very large in scale and will take time. Work to establish a possible mechanism is already advanced – the science is good – but that does not provide a definitive answer to the clinical issues of whether to use the vaccine (and in who) or not. What is certain, however, is that the risk of this adverse outcome, even if directly causal, is much lower than remaining unimmunised. The desire for an answer before it can be provided has meant that many will not receive that message with enthusiasm.

This is a well-established problem in regulatory matters. In 2016 more than 140 scientists made an appeal to law-makers to embed rules of evidence for the appropriate use of the scientific method in order to ensure that the integrity of the science was preserved when data were invoked in satisfying both the requirements of administrative policy and regulations and the ethical integrity of public policies and regulators[1]. Support for the appeal reflected concern with the erosion of scientific principles with data used inappropriately to simulate and exaggerate hazards and risks, undermining public confidence in both science and government, and sometimes leading to misallocation of resources. Other concerns were related to lack of reproducibility of data and the use of non-compliant or decades-old discredited studies to legitimise government interventions.

[1] See ‘An Appeal for the Integrity of Science and Public Policy’, Toxicology 371, 2016; and, Aschner M., Autrup H. N., Berry Sir Colin et al ‘Upholding science in health, safety, and environmental risk assessments and regulations’, Toxicology 371, 2016.

In attempting to satisfy these objectives, and to develop a set of principles and guidelines for scientific integrity that can be adopted and used by national governments and the European Union, four areas were examined in collaboration with the European Regulation and Innovation Forum (ERIF): study quality, the interpretation and assessment of studies, the way in which communication of scientific opinions to risk managers was performed, and the selection for eminent and relevant experts to undertake scientific assessments.

The detailed principles and guidelines for scientific integrity derived from this work were published in a peer-reviewed journal in 2020[2]. They are further reproduced in this ERIF Communication.

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April 2021

[2] Berry Sir Colin 'Frameworks for evaluation and integration of data in regulatory evaluations: The need for excellence in regulatory toxicology', Toxicology Research and Application, Volume 4, 2020.

SCIENTIFIC INTEGRITY IN REGULATORY STUDIES – PRINCIPLES AND GUIDELINES

1. INTRODUCTION

1.1. This text focuses on:

- Scientific assessments used to inform risk management decisions made by governments to provide a high level of protection of human health and the environment;

- The nature of the evidence assessed for this purpose, provided primarily by the findings of regulatory toxicology and epidemiology; and,

- The role of these data in safety testing of new or existing substances, technologies or materials, as well as experimental, 'investigative' studies[3] in identifying and evaluating new hazards or in challenging the existing body of risk management knowledge.

1.2. Objectives

- To provide a set of principles and guidelines that, if implemented properly, will help strengthen the integrity, quality, and consistency of scientific assessments used as part of the process of public management of technological risks; and,

- To ensure that opinions derived from scientific assessments are based on the available body of relevant, reproducible, and testable evidence provided by toxicology, and related fields of scientific endeavour, enabling risk managers to base decisions on reliable evidence[4].

1.3. Challenges

- The complexity of the risks posed by technologies to human health or the environment means that there is rarely a single study or determinative experiment that is capable of resolving all risk management issues. High quality decisions require the aggregation of multiple sources of evidence.

- In most jurisdictions, risk managers are required to consider all potentially relevant studies. This requirement and the evaluation of what is relevant poses problems for ensuring scientific integrity.

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[3] In general, this term refers to studies designed to test hypotheses that are not performed to agreed international protocols.

[4] Scientific assessments combine a critical evaluation of evidence (including data) with expert judgement. They are evaluations of a body of scientific or technical knowledge that typically synthesises multiple factual inputs, data, models, assumptions and best professional judgements to bridge uncertainties in the available information. Such assessments include, but are not limited to state-of-science reports; technology assessments; weight-of-evidence analyses; meta analyses; health, safety or ecological risk assessments; toxicological characterisations of substances; integrated assessment models; hazard determinations; or exposure assessments. (Source: derived from a definition used by the US Office of Management and Budget).

- Modern industry-funded safety research must satisfy quality standards and controls defined by regulators and comply with the demanding standards laid down in internationally accepted guidance (OECD, ICH et al) – the extent of compliance of these guidelines defines the quality of such studies and assists in the assessment of their value.

- Many experimental, 'investigative' studies do not comply with accepted regulatory guidance and internationally accepted standards – a problem increasingly recognised by leading journals and universities. These studies may inform about potential mechanisms of harm but their lack of reproducibility means that they are not useful within the regulatory decision-making process.

- 'Open Science' publishing may offer the possibility of speeding up the availability of findings from scientific research. At its best, it makes feely available high quality studies that have undergone rigorous review (so-called "open source" publishing"). However, at its worst, it could trigger waves of social concern about alleged hazards identified by low quality or misleading studies that have not been reviewed independently or replicated, and may well have been misinterpreted.

- Out-of-date studies, some several decades old, continue to influence risk perceptions and hence regulatory interventions. Many older studies fail to reflect modern scientific understanding or standards, or have been discredited or even retracted. In many cases such studies are unreliable and the raw data untraceable.

- Questionable research practices are increasingly evident, as major journals ('Science' and 'Nature') have emphasised the need for documentation of protocols to enable studies to be replicated. Errors include outcome reporting bias, selective reporting of research findings, protocol deviations not clearly described, data dredging, and citation bias.

- Some traditional bioassays (studies in whole animals), assessing chronic exposures or multiple modes of action or long-term hazards, lack scientific validity. Progress in scientific understanding of the mechanisms of adverse effects, notably in human carcinogenesis, has meant that regulators should exercise caution when considering evidence derived from a methodology that does not reflect the current understanding of the pathogenesis of particular events.

1.4. Coverage

This text sets out principles and guidance in four areas:

- Study Quality (see Section 2)

- Assessment of Studies (Section 3)

- Communication of Scientific Opinions to Risk Managers (Section 4)

- Selection of Experts (Section 5)

2. STUDY QUALITY

2.1. Principles

- All high quality studies must meet the basic precepts of the scientific method[5];
- Study design must be relevant and thereby able to answer the specific question posed by regulations or regulators; and,
- Premature, experimental studies that are not sufficiently tested and controlled should not form part of the body of data used in regulatory scientific assessments[6].

2.2. Guidelines[7]

- The study is conducted following a well-defined protocol - the protocol refers to specifications for the research process[8];
- The methodology follows appropriate standards applicable to the field of study – such as testing guidelines (ICH, OECD, US EPA, ECHA) and GLP standards;
- The results are relevant and applicable to the hypothesis being tested - conclusions answer the hypothesis. The results are not used to propose hypotheses that were not part of the initial research project;
- The study is designed and reported in such a way that anyone can repeat it using the same methodology and materials. Sufficient detail, so that others can repeat the study, should be part of the protocol and be included in the methods section;
- The study should include a Systematic Review[9] of previously produced related research - the evidence and conclusions are seen in the context of the existing body of evidence on the topic studied[10];

[5] The scientific method is an empirical method of acquiring knowledge. It involves careful systematic observation and experimentation, inductive and deductive reasoning and the formation and testing of hypotheses. Rigorous scepticism about what is observed must be applied, as cognitive assumptions may affect the interpretation of the observations. For discussion, see Popper, Karl R. 'The Logic of Scientific Discovery' London: Hutchinson, 1968.

[6] This is, for example, a particular problem with findings derived from small-scale animal studies or evaluation of exposure to chemicals at unrealistically high levels of exposure.

[7] These guidelines apply primarily to investigative studies undertaken to identify new hazards or to challenge the existing body of risk management knowledge. Safety testing undertaken or funded by producers of substances, materials or technologies must comply with legal requirements. Many of these are set out in substantive guidance by regulators or international organisations.

[8] Exhaustive information about Good Laboratory Practice (GLP) can be found on the websites of the OECD and the European Commission. These sites define a set of rules and criteria for the manner in which non-clinical health and environmental safety studies are planned, performed, reported, and archived.

[9] See for example, Smith V, Devane D, Begley CM, et al 'Methodology in conducting a systematic review of systematic reviews of healthcare interventions' BMC Med Res Methodol 11, 15 (2011). http://doi.org/10.1186/1471-2288-11-15

[10] This is a requirement for studies used to inform regulatory decision-making.

- All data generated must be critically analysed and the weight of the data generated considered, even if outliers are subsequently excluded. The evidence should be analysed critically, as opposed to a simple data collection;

- All data used in the analysis should be available to any researcher for the purpose of reproducing or extending the analyses[11];

- A materials and methods section should be included in the study findings – it provides sufficient detail to allow replication of the study;

- The statistical methods used are described with enough detail to enable a qualified reader with access to the original data to verify the results – disclosures of statistical methods meet the standards set out by leading journals, such as 'Nature' and 'Science';

- All data and the protocol are deposited in an approved repository – it is made publicly available without restriction, excepting reasonable controls related to human privacy or biosafety, and respecting relevant data protection laws;

- The conclusions should be supported by the data gathered, analysed and reported - they are not based on anything other than those data gathered and analysed as part of the study. Conclusions are well founded, based on relevance of the experimental design, statistically significant evidence and causality, when applicable;

- The study has been opened to expert scrutiny - peer review increases the probability that a study is properly conducted and conclusions are based on a credible, reasoned interpretation of the data generated by the study;

- The specific hypothesis and appropriate research methodology are disclosed and clearly explained - the hypothesis sets out the purpose of the research which should form the basis of all scientific activity. Hypotheses are based on scientifically plausible scenarios that a certain effect may occur; and,

- Funding, affiliations, and additional interests of authors should be disclosed - transparency allows other scientists, policy-makers and the public to better understand the motivation behind a study, as well as the context in which it was performed;

[11] This may not be possible in some cases, if studies are given confidential status by regulators, thereby protecting data and intellectual property.

3. ASSESSMENT OF STUDIES

3.1. Principles

- Assessments should be based on the weight-of-evidence. They should not be based on the findings of a single study, regardless of its origin or quality. Weight-of-evidence reviews should always be used when scientific questions can only be answered by using several different types of evidence. This is an important characteristic of decisions about the best way to manage risks to human health, public safety, or the environment[12][13];

- Novel hypotheses or non-validated methodologies should not influence findings of assessments unless supported by compelling scientific evidence;

- Further tests should only be sought by assessors if it is clear that the results will be relevant to the scientific assessment;

- Assessments should not address or be influenced by economic, social, ethical or other non-scientific factors when characterising risks to human health, public safety or the environment;

- Use of the Precautionary Principle should be limited to the selection of risk management measures. It should not inform or shape assumptions, defaults, methods or procedures used in assessments of scientific studies. Interpretation and use of the Precautionary Principle should follow the European Commission's Communication[14]; and,

- Unless mandated by legislation, findings from assessments should not explicitly recommend or include risk management measures;

3.2. Guidelines

- The assessment methods and procedures correspond to best international practices and accepted standards;

- A Systematic Review is performed to agreed standards (those of the Cochrane Collaboration, for example) to assess quality and relevance of all reliable studies that could inform the outcome of the assessment. This includes all positive and negative studies, and may be a legal requirement;

- The Review gathers all potentially relevant studies; provides a transparent basis for excluding low quality or irrelevant studies; and 'scores', using agreed and pre-stated criteria, studies that will form part of the weight-of-evidence review. Assessment of study

[12] Weight-of-evidence is an expert process of collecting evidence, assessing, integrating and weighing it to reach a conclusion, with a predefined degree of confidence, on a particular problem. It meets predetermined standards and considers all relevant evidence, both positive and negative, taking into account factors such as strength, relevance, and quality. It identifies conclusions that are best supported by the available body of evidence. It should always be used when scientific questions can only be answered using several different pieces of evidence.

[13] Guidance on the use of weight of evidence approach in scientific assessments is found in EFSA Journal 2017; 15(8); doi: 10.2903/j.efsa.2017.4971.

[14] European Commission 'Communication from the Commission on the Precautionary Principle' (2000, COM (2000) 1).

'quality' recognises compliance with regulatory guidelines; agreed standards of quality for investigative studies; and the 'power' of the journal within which an investigative study is published;

- A weight-of-evidence review is then undertaken, using the studies identified by the Review. It examines all relevant and high quality positive and negative studies that meet pre-determined criteria for selection. It meets predetermined standards of quality; and, it is undertaken in a transparent manner, including the provision of a clear formulation of methodology. Assessments based on the weight of available scientific evidence ensure that individual studies of questionable quality or reproducibility do not have a disproportionate impact on risk evaluation or mitigation measures;

- The weaknesses of old or superseded studies are recognised explicitly in the weight-of-evidence review. It treats evidence from older long-term chronic exposures, multiple modes of action or the long-term hazards derived with caution, and an appropriately conservative weight is applied to them. A similar approach is taken to studies that are not compliant with relevant protocols such as GLP. It recognises the limitation of correlation as opposed to causation based on a plausible mechanism of action;

- Relevant uncertainties are systematically identified, analysed and documented;

- The findings of assessments must be consistent with all available high quality relevant data and knowledge, including positive and negative findings; and,

- The assessments and their findings must be understandable to experts and be reproducible.

4. COMMUNICATION OF SCIENTIFIC OPINIONS TO RISK MANAGERS

4.1. Principles

- Communication of the findings of assessments to risk managers should be understandable, clear, and supported by the data gathered;

- High quality communication contributes to transparency and public trust in risk analysis: characteristics of good regulatory governance; and,

- Sufficient explanation and evidence should be provided to enable a similarly qualified and equipped scientist to reproduce the findings and conclusions.

4.2. Guidelines

- The communication of the findings of assessments ensures that risk managers are fully aware of the meaning of scientific advice; methodology and evidence on which conclusions are based; and, limitations of the validity of conclusions, including relevant uncertainties;

- The overall reporting ensures that there is transparency in all aspects, including data, study design, information, calculations, assumptions, and methodologies;

- The strategies and processes for identifying and acquiring studies, information, and data are documented and transparent;

- The criteria used for critically evaluating studies, data and information, along with their application, are fully explained and transparent;

- The limitations related to the data, studies, and information used in the assessment are explained, and gaps in the state of scientific knowledge are highlighted;

- The evidence and expert judgement is properly presented, explained, and documented, including methodologies used to reconcile inconsistencies in scientific data;

- The limitations of novel hypotheses or non-validated methodologies are acknowledged and documented;

- The reporting of uncertainties avoids hypothetical speculation, recognises that uncertainty is inherent to the nature of scientific evidence, and identifies resolvable issues that lie within the scope of existing requirements and require further investments in science. Where appropriate contextual information is provided;

- Sufficient information is provided on the data, information, and studies to allow a clear understanding of the rationale of the opinion;

- Any dissenting opinions are noted and reported, along with an accompanying rationale;

- New evidence that might alter the conclusions reached in the assessment is highlighted; and,

- Value judgements are avoided, including the framing of risks and commentaries on the social or political acceptance of risk, and the opinion focuses solely on scientific evidence and scientific advice.

5. SELECTION OF EXPERTS

5.1. Principles

- The primary objective of any selection process is to ensure that the best available experts undertake scientific assessments. They should meet accepted standards, for the determination of their expertise and the relevance of that experience to the issues to be considered.

- Bias, or the failure to act impartially and in the public interest, can result from conflicts of interest. These are multiple and encompass materialistic factors (such as financial gain), beliefs and ideologies, political affiliations, and personal factors, including ambition, family history, power, and status. They are part of the human condition.

- Appropriately qualified experts should not be excluded from joining scientific committees or panels simply because they have one or more demonstrable conflict of interest.

- Rigorous, fair, and transparent processes should be employed to identify and disclose all forms of material conflict of interest that are likely to be relevant to the specific work of the expert group, committee, or panel.

- Genuine scientific disagreement, if based on well-founded scientific evidence, does not constitute a conflict of interest. Evidence of intellectual debate and differences of opinion are part of the scientific process but so is the resolution of these difficulties in the light of new evidence.

- Stakeholders of all types should be encouraged to make use of high quality scientific evidence and advice when informing their respective positions, and this information should be made available to inform broader societal debates.

- Undertaking paid work for industry or for activist groups (or research institutes that pursue a specific social or political agenda) is not, on its own, grounds for exclusion from serving on advisory groups, panels or committees.

5.2. Guidelines

- Committees or panels are institutionally independent, and separate from political influence;

- Committees or panels are constituted so as to ensure that decision-makers have access to an appropriate range of relevant different types of scientific expertise from different scientific disciplines and relevant practical technical expertise;

- As a general rule, committees or panels undertaking scientific assessments seek to manage conflicts of interest rather than exclude appropriately qualified experts;

- Experts are only excluded from specific scientific assessments if one of the two following conditions are met: (i) there is clear and substantial evidence of predetermination[15]; or, (ii) there is a credible likelihood of direct, material financial gain[16];

- Experts selected to carry out scientific assessments commit formally to act impartially, and in the public interest;

- Whilst respecting intellectual debate and commercial confidentiality, there is a presumption of openness throughout the process;

- Outcomes of scientific assessments are subject to independent peer review. All draft assessments should be reviewed procedurally, whilst significant assessments should be subject to an additional substantive review.

[15] This condition is satisfied if there is substantial evidence of personal beliefs, commitments, perspectives, or intensely advocated policy positions that suggest predetermination, where an advisor is committed to a particular point of view and unwilling or reasonably perceived to be unwilling to consider other perspectives or relevant evidence to the contrary. (Source: derived from a definition used by the US National Academies of Science).

[16] For this condition to be satisfied there must be credible likelihood that direct, material financial gain for the advisor of his/her immediate family or employer, be that industry, academic institution or NGO, will result from a certain opinion.

Appendix A

Epidemiological Studies

1. Epidemiology is the study of the pattern of disease in humans:

- Its most effective role is to conduct investigations of occupational and other restricted settings where exposures and externalities are amenable to measurement and to provide tentative clues about causation that other scientific investigations may illuminate;

- It is important to emphasise that epidemiology identifies associations not mechanisms of causation;

- The weight that might be attached to these associations varies, and the way in which they are evaluated should follow internationally accepted guidelines. There are well-established and robust systems that include the following critical points:

2. Guidelines[17]:

- The aim of study is defined in advance and published – it includes a specific hypothesis or research question to be tested;

- The study is based on a detailed research protocol that describes the study and is deposited publically prior to commencement – the level of detail allows another study group to carry out the study as intended;

- The study is carried out in accordance with the protocol and all deviations are documented and reported;

- The statistical analysis is carried out in accordance with the study protocol - additional analyses undertaken but not foreseen when the study protocol was registered are identified as such in the final report;

- No changes are made to the raw dataset once the statistical analyses commence;

- The final report is an accurate, balance, and concise reflection of the study – it also describes its limitations and any deviations from the protocol;

- All results are properly reported and disclosed – the study is rigorously documented and archived such that a trained scientist, not necessarily an epidemiologist, can reconstruct how the study was documented;

- Once the report is finalised, the raw data files and final dataset used for statistical analysis is stored securely – a full explanatory data description is stored and the privacy of subjects is protected.

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[17] See Swaen GMH, Langendam M, Weyler J, Burger H, Siesling S, Atsma WJ, and Bouter L 'Responsible Epidemiological Research Practice: a guideline developed by a working group of the Netherlands Epidemiological Society' in Journal of Clinical Epidemiology 100 (2018) 111-119; Stroup DF, Berlin JA, Morton SC et al 'Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis of Observational Studies in Epidemiology (MOOSE) group' JAMA 2000; 283: 2008-2012; Dekkers OM, Vandenbroucke JP, Cevallos M, Renehan AG, Altman DG, Egger M, 'COSMOS-E: Guidance on conducting systematic reviews and meta-analyses of observational studies of otiology' PLoS Med 2019; 16: e1002742; and Mueller M, D'Addario M, Egger M, et al 'Methods to systematically review and meta-analyse observational studies: a systematic scoping review of recommendations' BMC Med Res Methodol 2018; 18: 44.

European Regulation and Innovation Forum

The European Regulation and Innovation Forum (ERIF) is an expert-led and not-for-profit think tank with the aim of promoting high quality decision-making by the EU institutions through Better Regulation. The ERIF was known as the European Risk Forum until January 2021.

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory governance, decision-making structures, tools, and processes; the risks and benefits of new and emerging technologies, and of lifestyle choices; obstacles and incentives for innovation, including the regulatory framework; and, the importance of high quality scientific evidence for better regulation. This approach is highly relevant at present, as the EU recovers from the COVID-19 pandemic and undertakes an effective and proportionate transition to the new economic and societal models pursued by the European Green Deal.

Better Regulation is one of the pre-conditions for delivering these goals. It seeks to strengthen consent to law-making and to the actions of the State needed to implement legal requirements. Accordingly, laws and regulations should be:

- Necessary, effective, and proportionate (resting on a rigorous definition of the policy objectives, as well as a clear and comprehensive description and assessment of problems and their underlying causes);
- Based on credible evidence, particularly science, that supports the use of the powers of the State;
- Informed by a robust and transparent understanding of costs and benefits, particularly dynamic impacts such as risk-risk tradeoffs;
- Demonstrate that benefits justify costs;
- Developed using transparent and participatory decision-making processes; and,
- Reviewable over time and subject to appeals and redress mechanisms

High quality decision-making, notably risk regulation, should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, costs, benefits, and legitimacy of different policy options (risk management).

Achieving these goals is likely to require extensive use of evidence (especially science); rigorous definition of policy objectives; clear and comprehensive description and assessment of problems and their underlying causes; realistic understanding of the costs and benefits of policy options; and extensive consultation.

These principles and requirements form part of the approach to regulatory decision-making set out by the OECD since 1995. The approach to risk regulation promoted by the WTO also makes explicit reference to these principles and practices.

The ERIF is supported principally by the private sector. The ERIF does not seek to promote any specific set of values, ideologies, or interests. Instead, it considers high quality risk assessment and risk management decisions as being in the public interest. An advisory group of leading academics supports the ERIF's work.

The Forum works with all EU institutions to promote ideas and debate. Original research is produced and is made widely available. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practitioners and policy-makers; non-EU good practices; and academic research) to assess issues and to identify new ideas. The ERIF directly engages in EU regulatory reform debates through targeted lunches and roundtables. The Forum also regularly contributes to public consultations launched by the EU institutions. A key feature of the ERIF's approach is its emphasis on expert-to-expert dialogue to share views and learn from good practice.

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