European Radiology (2019) 29:4794–4802
https://doi.org/10.1007/s00330-019-06105-y

IMAGING INFORMATICS AND ARTIFICIAL INTELLIGENCE

Clinical trials in radiology and data sharing: results from a survey of the European Society of Radiology (ESR) research committee

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Received: 23 November 2018 / Revised: 5 January 2019 / Accepted: 12 February 2019 / Published online: 27 February 2019

Abstract

Objectives To determine the current situation and future directions of clinical trials and data sharing in radiology.

Methods This survey was conducted between July and September 2018 among European heads of imaging departments and speakers at the Clinical Trials in Radiology sessions at ECR 2015–2018. The survey was approved by the ESR research committee, was administered online, and chi-square tests were used.

Results The overall response rate was 29% (132/460). Responses were received from institutions in 29 countries. These institutions reported having conducted 429 trials, leading to 332 publications, of which 43% were first and 44% were last authorships by those institutions. For future trials, 98% of respondents (93/95) said they would be interested in sharing data, although only 34% had shared data already (23/68, $p < 0.001$). The major barriers to data sharing were data protection (78%, 74/95), ethical issues (49%, 47/95), and the lack of a data sharing platform (49%, 47/95). Of the respondents, 89% believed a platform would facilitate data sharing (85/95 vs. 10/95 did not, $p < 0.001$) and should offer easy data uploading (74%, 70/95), data safety (66%, 63/95), easy communication between providers and re-users (62%, 59/95), and data access policies (56%, 53/95).

Conclusion A considerable number of imaging trials are being performed and published by radiologists in Europe whilst data sharing is hardly taking place, despite great interest. This is most likely due to data protection and ethical issues, as well as the absence of a data sharing platform.

Key Points

- *Radiologists have performed a considerable number of more than 400 imaging trials in the last 5 years.*
- *Although only 34% of institutions had shared trial data already, 98% are interested in doing so.*
- *Major data sharing barriers are ethics, data protection, and the absence of a sharing platform.*

Keywords Randomized controlled trial · Clinical trial · Diagnostic imaging · Information dissemination · Surveys and questionnaires

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00330-019-06105-y) contains supplementary material, which is available to authorized users.

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Abbreviations

ECR	European Congress of Radiology
EIBIR	European Institute for Biomedical Imaging Research
ESR	European Society of Radiology
GDPR	General Data Protection Regulation

Introduction

Randomised trials are a key contributor to evidence-based medicine and radiology plays an increasingly important role in developing evidence-based strategies for diagnostic management and image-guided treatments [1]. This may assume an even greater role in the light of the shift towards value-based radiology [2]. The extent to which radiologists are involved in the planning, conduct, and publication of randomised imaging trials has been understudied. Involvement in such imaging trials comparing different diagnostic imaging strategies or image-guided therapies, in addition to medical randomised trials with imaging as a contributor, will be critical for the future of our field as it is important to be part of discussions when decisions about clinical strategies for defined patient groups are made.

The International Committee of Medical Journal Editors has recently recommended that data sharing be considered by randomised trial authors [3] but it is rarely included in the policies of radiology or general medical journals [4]. Moreover, a recent review of two medical journals with a full-data sharing policy showed that only 46% of trial data were made available [5]. These facts may lead to an underutilisation of the enormous wealth of data that is present in randomised imaging trials despite efforts such as the European Open Science Cloud pilot project [6]. More widespread implementation of data sharing may result in the availability of higher evidence levels for recommendations to be included in guidelines [7] and help to alleviate the so-called reproducibility crisis that may be overcome by greater replication efforts [8]. Importantly, however, the pivotal contribution and insights of trial organisers and participants must not be forgotten by data scientists re-analysing trial data. Incentives should be created to encourage data sharing in the field of radiology. Data safety and ethical concerns about data sharing are barriers to sharing data and these issues need to be addressed [9].

Thus, we conducted an online survey among European heads of imaging departments and speakers at the Clinical Trials in Radiology sessions at the European Congress of Radiology (ECR) 2015–2018 to ascertain the current situation and anticipate future directions of imaging trials and data sharing in radiology.

Materials and methods

Survey design

This survey was conducted from Monday, 16 July to Saturday, 1 September, 2018, among 428 European heads of imaging departments and all 32 participants of the Clinical Trials in Radiology sessions at ECR between 2015 and 2018. The survey was developed by a core team at the Charité – Universitätsmedizin Berlin and the Department of European and International Affairs at the European Society of Radiology (ESR) and was approved by all members of the ESR Research Committee Board.

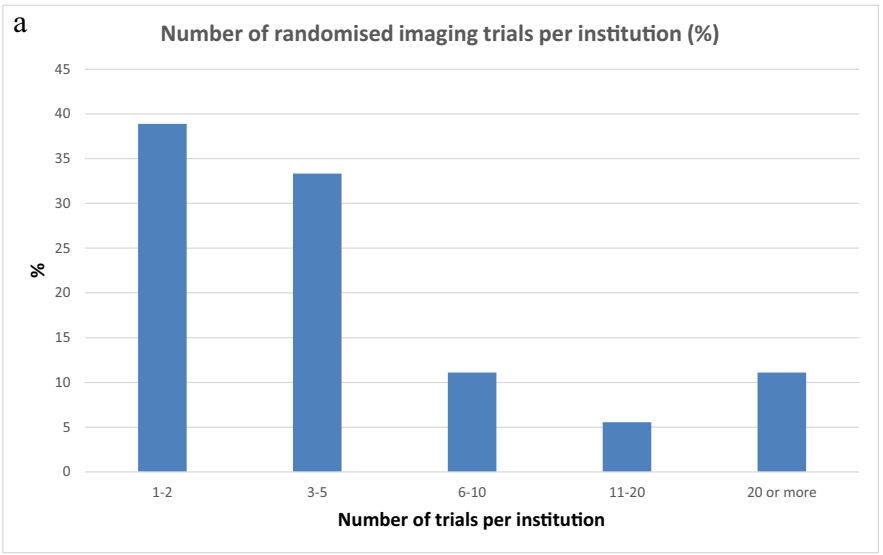
Survey content

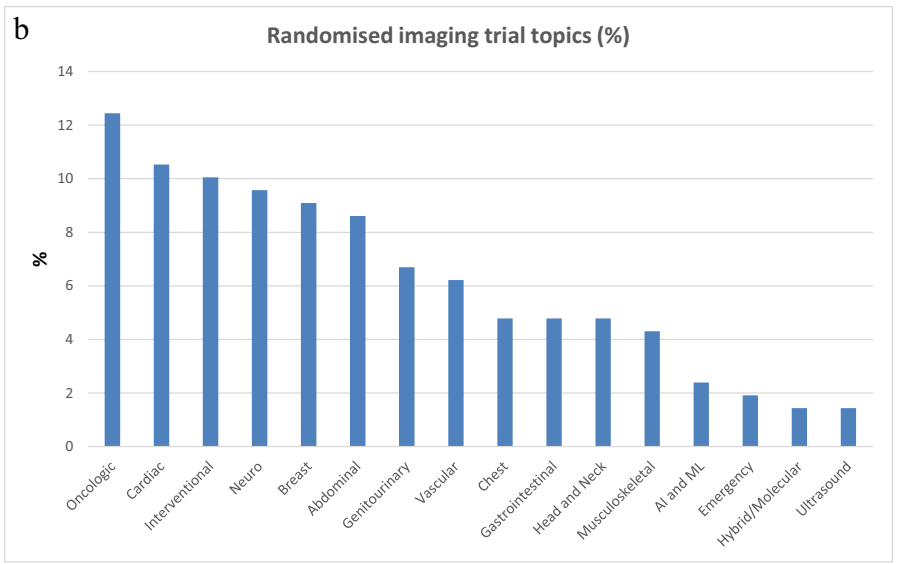
This survey was separated into questions that covered (1) general questions such as geographic information about participants' institutions (countries), type of institutions (University hospital, general hospital, teaching hospital, research facility), and local clinical research set-up (number of study nurses); (2) randomised imaging trials, such as participation by respondents in and motivation for such trials, reasons for not participating in imaging trials, circumstances under which participation could be possible, type of randomised imaging trials (single-centre, multicentre), funding for imaging trials (foundations, state agencies and European agencies, or medical industry), radiologists as the principal investigator, topics of randomised imaging trials, publications derived from these imaging trials, and authorships for institutions; (3) data sharing from own imaging trials performed in the last 5 years, type of data shared, publications derived from such data sharing and co-authorships for institutions, and reasons for not sharing data from trials undertaken in the last 5 years, data sharing of future imaging trials, willingness to share data, incentives to share data, barriers to data sharing, and platform for data sharing; (4) presence of access to data from randomised imaging trials done elsewhere in the last 5 years, interest in such access, reasons for interest, incentives for providing data to others, barriers for getting access, and data sharing platforms; and (5) interest in participating in randomised imaging trials in general, ability to randomise patients for certain topics, and interest in sharing data from randomised imaging trials.

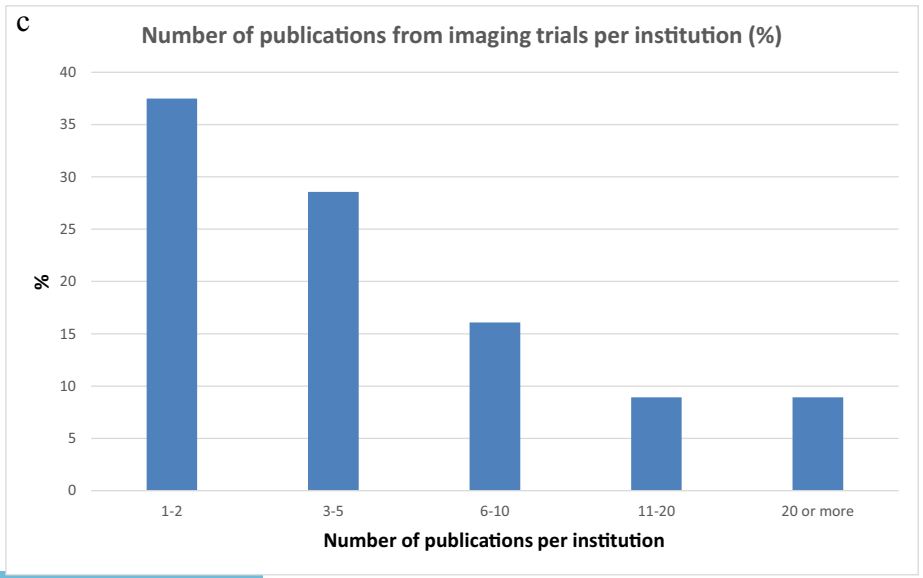
The full surveys sent can be found in the Electronic Supplementary Materials 1 and 2.

Survey administration

This survey was conducted using an online tool (Survey Monkey). This allowed logic to be applied to the survey, i.e. appropriate subquestions to be asked after the main questions. For example, certain questions, e.g. 'has your department participated in randomised imaging trials in the last 5 years?' (answer: yes/no), would lead the respondent to different supplementary questions depending on the answer given. As a consequence, not all the questions in the survey were presented to all respondents. Furthermore, as not all questions were mandatory, some respondents chose not to answer all the questions they were presented with. This accounts for the variations in the number of respondents to different questions.







◀ **Fig. 1** Data about randomised imaging trials (**a**), trial topics (**b**), and resulting publications (**c**). **a** The questions of how many trials were conducted were answered by 72 out of the 94 institutions that reported participating in trials. The majority of sites were involved in five or fewer trials (1–2 trials (39%, 28/72), 3–5 trials (33%, 24/72)). The minimum total number of trials conducted at all of the responding institutions was 429, with 11% of sites reporting participation in 20 or more trials (8/72). Of the remaining sites, 11% reported participating in 6–10 trials (8/72) and 6% in 11–19 trials (4/72). (**b**) The most common trial topics were oncologic imaging (12%), cardiac radiology (11%), interventional radiology and neuroradiology (each 10%), and breast and abdominal viscera (each 9%). Less common trial topics were genitourinary (7%), vascular (6%), chest, gastrointestinal, and head and neck (each 5%), musculoskeletal (4%), artificial intelligence and emergency radiology (each 2%), and hybrid/molecular imaging and ultrasound (each 1%). **c** The question of how many publications were derived from randomised imaging trials was answered by 69 out of 94 respondents. Of those 69 institutions, 56 derived publications from their randomised imaging trials. Thirteen of the 69 institutions did not derive any publications from their randomised imaging trials. The trials led to a minimum of 332 publications: the majority of institutions reported publishing between one and five original works based on their randomised imaging trials: 38% (21/56) reported publishing 1–2 original works, whilst 29% (16/56) reported publishing 3–5 works. Of the remaining institutions, 16% (9/56) reported publishing 6–10 works whilst 9% (5/56) reported publishing 11–20 works, with a further 9% (5/56) reporting over 20 publications

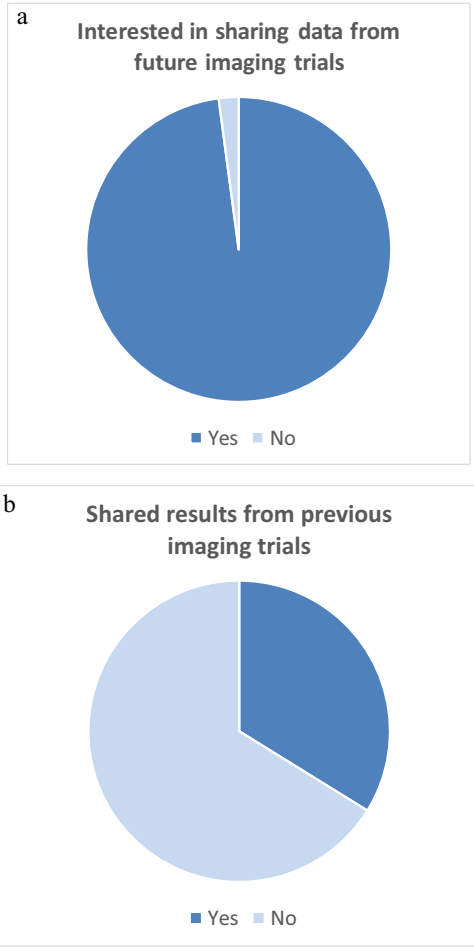


Fig. 2 Difference in interest and prior participation in data sharing. For future trials, 98% of respondents (93/95) said they would be interested in sharing data (**a**). However, only 34% had previously shared data (**b**, 23/68, $p < 0.001$). Overall, 66% of institutions (45/68) had not shared trial data in the last 5 years with other researchers for scientific re-use after results were published (no response was received to this question from 64 institutions). Reasons for not sharing data were no request to share data (69%, 31/45), ethical issues (29%, 13/45), no platform for imaging trials data sharing (22%, 10/45), and no patient consent (18%, 8/45)

Survey reminders

The invitation to participate in the survey was first sent on Monday, 16 July, 2018, with a deadline for completion by Monday, 30, July, 2018. A reminder email was sent by the Department of European and International Affairs of the European Society of Radiology (ESR) on Monday, 30 July, 2018. Additionally, the survey deadline was extended, at first until Friday, 3 August, 2018, then Tuesday, 21 August, 2018, and was finally further extended by email until Saturday, 1 September, 2018. It was decided to offer these extensions due to the survey being conducted at a time at which many potential respondents were on vacation.

Statistical analysis

For the prevalence of responses, descriptive statistics were used and comparisons were performed using chi-square tests. We performed all analysis with the statistical software SPSS (version 22, IBM).

Results

Participation and institutions

The response rate was higher among Clinical Trials in Radiology session speakers (56%, 18/32) than department heads (27%, 114/428; $p < 0.001$). Responses were received from 132 institutions in 29 countries (Italy, 22; Germany, 14; Turkey, 11; France, 10; Netherlands, 7; Bulgaria/Romania/Sweden, 6 each; UK/Spain, 4 each; Belgium/Norway/Poland, 3 each; Croatia/Denmark/Estonia/Greece/Hungary/Israel/Lithuania/Portugal/Switzerland, 2 each; Austria/Czech Republic/Finland/Ireland/Latvia/Russia/Slovakia, 1 each; 8 respondents did not provide a country response). The question 'How many study nurses/assistants currently work in your department?' revealed that at least 976 study nurses worked at the 130 institutions which responded to the question (28 institutions with 21 or more study nurses, 15 with 11–20, 21 with 6–10, 23 with 3–5, 28 with 1–2, and 15 institutions with 0 nurses).

Randomised imaging trials

Overall, 71% of institutions (94/132) had participated in trials in the last 5 years and the majority of sites were involved in between one and five trials (Fig. 1a). Of the

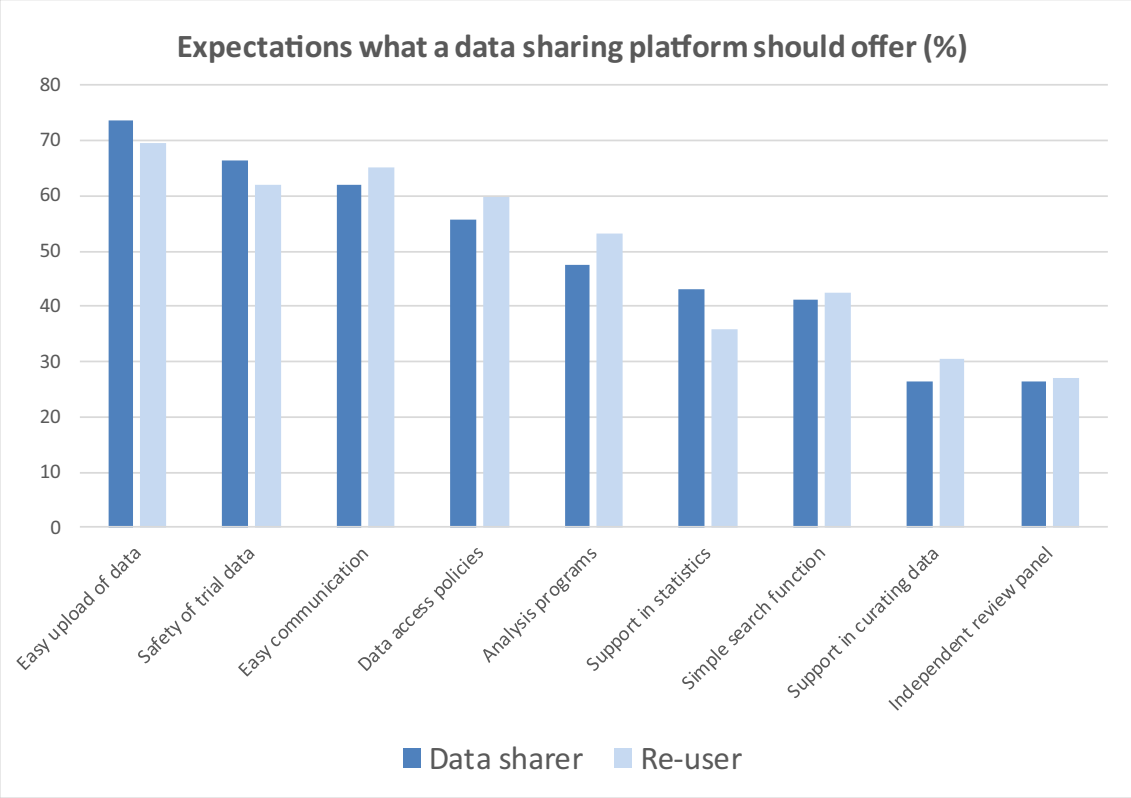


Fig. 3 Expectations towards an imaging trial data sharing platform from the perspective of sharers and re-users. Expectations showed no relevant differences. For data re-users: among the respondents, 93% believed that a platform would facilitate getting access to data from trials of other departments (86/92) whilst no platform for data sharing was provided as the main reason for not sharing data only in 22% (Fig. 2). A data sharing platform should offer the following: easy upload of data (70%, 64/92), safety of trial data (62%, 57/92), easy communication between providers and re-users (65%, 60/92), data access policies (60%, 55/92), analysis programs, e.g. DICOM and R (53%, 49/92), support in statistical analysis (36%, 33/92), simple search function (42%, 39/92), support in curating data (30%, 28/92), and independent review panel for access decisions (27%, 25/92). For data sharers: Among the responding institutions, 89% believed that a platform would facilitate data sharing (85/95 vs. 10/95 did not, $p < 0.001$) and should offer the following: easy upload of data (74%, 70/95), safety of trial data (66%, 63/95), easy communication between providers and re-users (62%, 59/95), data access policies (56%, 53/95), analysis programs, e.g. DICOM and R (47%, 45/95), support in statistical analysis (43%, 41/95), simple search function (41%, 39/95), and an independent review panel for access decisions and support in curating data (both 26%, 25/95)

429 trials which were reported, 214 (50%) were funded by the medical industry and 159 (37%) by foundations, state agencies, or European agencies. Motivations for participating in randomised imaging trials were reported as being scientific interest (64/94 [68%]), authorship (35/94 [37%]), fostering collaboration (27/94 [29%]), and financial incentives (24/94 [26%], Table S1, multiple motivations could be provided per institution).

The survey showed that 26% of institutions (35/132) had not participated in randomised imaging trials in the last 5 years (3/132 institutions did not respond to this question). The main reasons for not participating were reported as not being requested to participate (71%, 25/35) and not having enough financial support (14%, 5/35, Table S2). For these institutions, the main circumstances under which they would be willing to participate in future trials would be scientifically interesting topics (60%, 21/35), greater financial support (37%, 13/35), and more European calls (29%, 10/35, Table S3).

Overall, 49% of the 429 trials had a radiologist as the principal investigator (210/429). The most common trial topics are summarised in Fig. 1b. The trials led to a minimum of 332 publications and the distribution of publications between the 56 institutions which reported having published their results is shown in Fig. 1c, with five institutions reporting over 20 publications. Of the 332 publications, 43% (144/332) were reported as being first authorships by the reporting institution and 44% (145/332) were reported as last authorships.

Data sharing from previous and future randomised imaging trials

Although only 34% had shared data already (23/68), for future trials, 98% of respondents (93/95, $p < 0.001$) said they would be interested in sharing data (Fig. 2). The most commonly shared data after results were published in the last 5 years were anonymised image data (91%, 21/

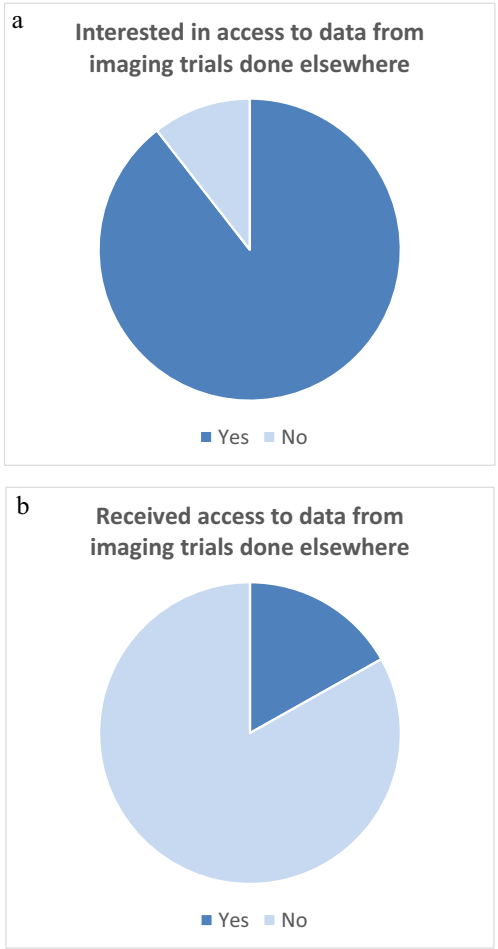


Fig. 4 Difference between interest in accessing data shared by other institutions in the future and previous access to data shared by other institutions. In contrast to the high interest (**a**) of institutions in getting access to data shared by researchers from other randomised imaging trials for scientific re-use (89%, 85/95), only 17% had accessed such data in the last 5 years (**b**, 16/95, $p < 0.001$). The main reasons given for the interest in getting access to other data were to test reproducibility of results (58%, 55/95), to enable individual patient data meta-analysis (54%, 51/95), and to derive intellectual property (28%, 27/95)

23). To a lesser extent, structured anonymised data from electronic case report forms was also shared (26%, 6/23, Table S4). At least 44 original works were published based on data shared by the 23 institutions that reported sharing their data. Five institutions reported one publication by other researchers based on data they had shared. Three institutions reported two publications by others based on data they had shared. One institution reported three publications based on data they had shared, another institution reported six publications based on data they had shared, two institutions reported seven publications based on data they had shared, and one institution reported ten publications based on data they had shared. All 13 institutions that provided data leading to publications were listed as co-authors (Table S5).

Among the responding institutions, 89% believed that a data sharing platform would facilitate data sharing (85/95 vs. 10/95 did not, $p < 0.001$). There was a strong correlation between what respondents expected such a platform to offer as an incentive for them to share data and what was expected by those seeking to re-use data (Fig. 3).

Access to data from previous randomised imaging trials

In contrast to the high interest of institutions in getting access to data shared by researchers from other randomised imaging trials for scientific re-use (89%, 85/95), only 17% had received access to such data in the last 5 years (16/95, $p < 0.001$, Fig. 4). The main reasons for the interest in gaining access to other data were to test reproducibility of results (58%, 55/95), to enable individual patient data meta-analysis (54%, 51/95), and to derive intellectual property (28%, 27/95).

The main incentives that re-users would be willing to provide to the original randomised imaging trial researchers in return for permission to access their data were somewhat different from interests mentioned from the perspective of data providers (Fig. 5). The major barriers mentioned for getting access to data from other trials were similar to the major barriers mentioned from the perspective of sharing data (Fig. 6).

Interest in future trials and data sharing

Overall, 92 out of 132 participants indicated their interest in participating in randomised imaging trials and, on a scale of 1–10, the median interest was 8, with an interquartile range of 7–9. The interest in sharing data of randomised imaging trials was similar with a median of 8 and an interquartile range of 6–9 on a scale of 1–10.

Discussion

This survey study was conducted to determine the current European situation and future directions of trials and data sharing in radiology. We found that a considerable number of imaging trials are being performed and published by radiologists in Europe while hardly any data sharing is taking place despite great interest. This is most likely due to data protection and ethical issues, as well as the absence of a data sharing platform, which was considered by 89% of respondents to the survey to be likely to facilitate data sharing. Incentives for sharing data are vital and we found some differences in this regard between data providers and re-users: for example in relation to expected financial remunerations and being mentioned in the acknowledgments. These results are of relevance as

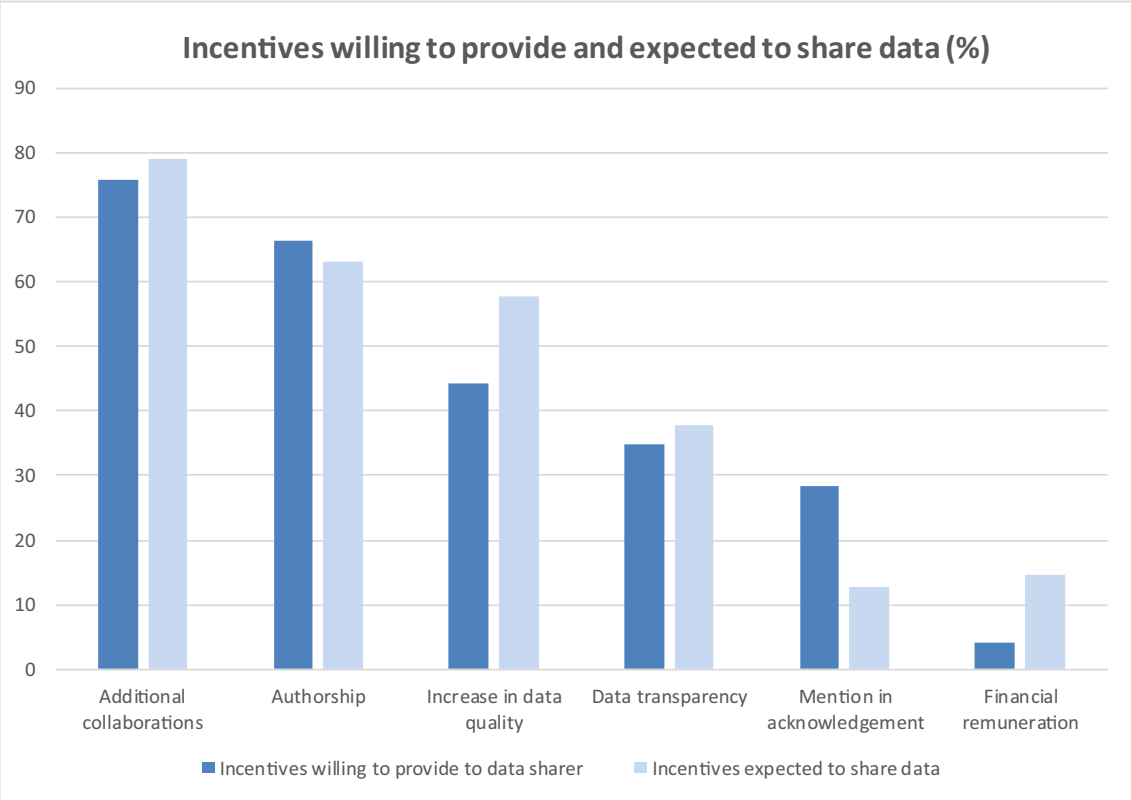


Fig. 5 Differences in re-users willingness to provide incentives for data sharing and expected incentives by researchers of future original randomised imaging trials ('data sharers'). The main difference was that there were significantly greater expectations for financial remuneration by data providers, with 15% (14/95) expecting remuneration versus 4% willing to provide it (4/95, $p = 0.013$). Additionally, being mentioned in the acknowledgments was less of interest to data sharers (13%, 12/95 vs. 28%, 27/95, $p = 0.007$). Other results indicated some common ground between data sharers and re-users (sharers of data: additional collaborations (79%, 75/95), authorship (63%, 60/95), increase in data quality (58%, 55/95), data transparency (38%, 36/95). Re-users of data: additional collaborations (76%, 72/95), authorship (66%, 63/95), increase in data quality (44%, 42/95), and data transparency (35%, 33/95))

randomised trials constitute the highest levels of evidence and could inform upon clinical practice guidelines [1].

We believe that this survey has two major policy implications. Firstly, further strengthening of efforts relating to funding for and conduct of randomised imaging trials by ESR and sub-speciality societies appears worthwhile as these trials are met with great interest by responding institutions. Also, the European Institute for Biomedical Imaging Research (EIBIR) and allied European societies may consider harmonising efforts towards more impactful trials on imaging technologies. Secondly, in order to make full use of imaging trials, we should also strengthen efforts to enable data sharing between different consortia conducting such trials as well as data sharing with scientists interested in re-analysis of imaging trials. For this, a data sharing platform is needed that should, among other features, offer easy upload of data (including images), safety of trial data, easy communication between providers and re-users, and data access policies [10]. We believe that the data protection standards used globally for such a platform should follow the more strict principles of the European General Data Protection Regulation (GDPR) [11, 12]. To successfully achieve data sharing, the implications of re-segmentation of data and re-extraction of functional imaging parameters need to be accepted at the point of data upload. Moreover, an open and global data sharing platform of imaging trials may have great value for the rapid growth in artificial intelligence [13, 14]. With the support of ESR, the first meeting of investigators participating in this survey who signalled interest in joining our global data sharing platform initiative 'Guide-IT' will be held at ECR 2019. Objectives of the Guide-IT initiative are the following: (1) a tailored and sustainable infrastructure for data sharing; (2) harmonised data and secured access for data quality and safety in data sharing; (3) generation of policies, rules, and standards for the protection of patient data and intellectual property rights; and (4) an interoperable and interconnectable infrastructure for the data sharing platform.

Data sharing has incredible potential to strengthen academic research, the practice of medicine, and the integrity of the clinical trial system [15]. Since data protection and ethical issues are mentioned as major barriers to data sharing by responding institutions, it will be important to ensure the safety of shared data and develop broad consent by participants or specific consent for data sharing for additional research. Stakeholders involved in data sharing initiatives should thus also include ethicists and data protection experts. Also,

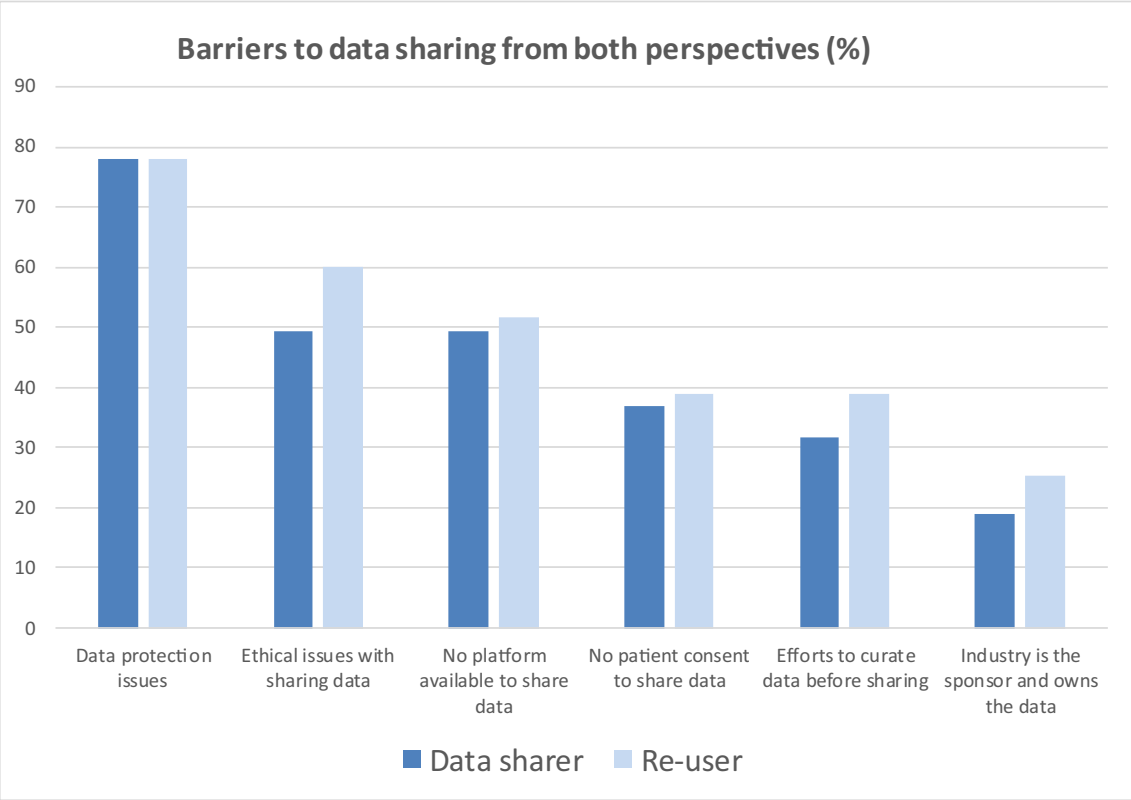


Fig. 6 Barriers to data sharing are similar from the perspective of sharing and re-using. From the sharer perspective, the major barriers to data sharing were data protection issues (78%, 74/95), ethical issues (49%, 47/95), no platform available upon which to share data (49%, 47/95), no patient consent to share data (37%, 35/95), efforts to curate data before sharing (32%, 30/95), and industry is the sponsor and owns the data (19%, 18/95). From the perspective of re-users, the major barriers to data sharing were data protection issues (78%, 74/95), ethical issues (60%, 57/95), no platform available upon which to share data (52%, 49/95), no patient consent to share data (39%, 37/95), and efforts to curate data before sharing (39%, 37/95). Both groups identified similar barriers to data sharing

barriers to data sharing were identified in our survey and in addition to the well-known aspects our data also suggest that it will be important to avoid in the future that industry blocks the path towards data sharing by considering ownership and rights to share data in research agreements.

The final goal to be aimed for through data sharing is improved patient outcomes based on better justified use of imaging technologies in the right patients at the right time. Thus, patient engagement and involvement of patient advisory groups both in imaging trials and data sharing initiatives have the potential to broaden the impact of such initiatives. Moreover, with the help of the current survey and participants who agreed to be contacted again about the development of a data sharing platform, the European nucleus of a data sharing project with possible global outreach has been formed. It is crucial that such infrastructure will be interoperable and connectable to other national and international structures [16].

The perspectives of patients collected from the views of trial participants were the focus of a recent special report indicating that patients are generally very positive about sharing trial data, with more than 90% approval rates, because of the potential to advance scientific knowledge and ultimately improve patient care [17]. This view was also recently highlighted in a perspective article on how patients can advance the data sharing debate [18]. A leading principle of the data sharing debate is the FAIR (findable, accessible, interoperable, reusable) principle [19]. A good example is the CORBEL (Coordinated Research Infrastructures Building Enduring Life-science Services) project which has developed principles and recommendations for sharing individual patient data from randomised trials [20]. These principles should receive greater attention by scientists but also by funding organisations [21]. Protecting personal patient data when image data are shared will be a major challenge for a data sharing platform as image data are more likely to become de-anonymised than other health data [22] and techniques such as de-facing will be critical [23].

This study has limitations. The survey was only conducted among European radiology institutions and results from a global survey might be different. Such a worldwide survey should be pursued as the next step. The response rate to the survey was limited, especially for department heads, but typical for what one would expect for an online survey. Nevertheless, the incomplete response rate makes the results limited to a sample that may not completely reflect the European radiological landscape.

Moreover, not all of those responding answered all questions in the survey further limiting the representativeness of the survey results. It is impossible to speculate what other perspectives might have emerged had the response rate been higher or had the survey been extended to other demographics. Also, no information about the publication types (e.g. scientific field, journal rank) was collected in the survey about the trial publications. Whilst the majority of research work in clinical trials is done by study nurses/assistants, also radiographers/technologists are involved and the number of them at the trial sites was not collected in this survey. We were also not able to identify if environmental factors such as the type of institution were related to the participation by responders in imaging trials.

In conclusion, this survey study shows that there are many randomised imaging trials undertaken and these are resulting in a significant number of publications. Radiologists play an important role as principal investigators and lead authors in about half of these studies. While there is great interest in sharing data generated by randomised imaging trials, and getting access to data from studies conducted by others, several barriers still need to be overcome to make widespread data sharing a reality.

Acknowledgements The abstract for this paper was accepted for the Clinical Trials in Radiology (CTiR) session of the European Congress of Radiology in Vienna 2019.

Funding The study received no funding.

Compliance with ethical standards

Guarantor The scientific guarantor of this publication is Prof. Dr. Marc Dewey.

Conflict of interest The authors of this manuscript declare no relevant relationships with companies and no conflicts of interest.

Statistics and biometry No complex statistical methods were necessary for this paper.

Informed consent Not required for this anonymised survey.

Ethical approval Not required for this anonymised survey.

Methodology
• Prospective

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