The need for Data Sharing in Rare Disease Research

Publication, Accessibility and Informed Consent

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Two speakers → different backgrounds

Short introduction

How to benefit from this lesson?

Some theory, lessons from experience, practical tips

Questions & discussion
Main issues in RD Research

• Many rare diseases (6000-8000)
• Few patients, specialists, data, bioresources
• High motivation in the patient community
• Special vulnerability of patients

• Need/Obligation to make the best use of available resources AND protect patient integrity
Data sharing: 3 key benefits

- Faster progress in improving health
- Better value for money
- Higher quality science

- A necessity in the field of RD research!
Strategic role of scientific communication

WHY IS IT SO IMPORTANT?

• What is your target?

• How do you disseminate your research/data?

• Are you aware of existing (editorial) rules?

• Are you aware of ethical issues?
Some points to consider:

- Progress is always based on previous work
- Scientists have a responsibility for communicating research results
- Patients need to be informed
- All stakeholders (policy makers, general public) should be aware of the value of scientific research
- Health is a common good
- We live in a “global” world
- Duplication allows to reduce waste

Communication (sharing) is an essential part of research
## Different targets, objectives & types of scientific communication

### Target
- **PEERS**
  - Researchers, medical & technical staff

- **LAY PEOPLE**
  - Patients, families, policy makers, community health workers, vendors, etc.

### Objective
- **Share research results, progress in research, contribute to debate**
- **Change behaviour, improve life style, access to therapy, increase retention**

### Type
- **Journal articles**
- **Technical reports**
- **Oral communications or posters in conferences or workshops**
- **Abstracts and proceedings**
- **Social media**
- **Repositories**
- **Oral communications**
- **Leaflets, bookmarks, posters**
- **Audiovisuals**
- **Workshops, informal meetings**
- **E-health communication**
- **Social media**
- **Networks**
- **Dynamic consent**
- etc.
New trends: BE OPEN!

WHAT DOES IT MEAN?

- Open sharing of research activity
- Open online information
- Open Access journals
- Open peer-review
- Open data sharing
- Open to patients/society
- Open in disclosure conflicts of interest
- Open online courses (MOOCs)

A NEW STATE OF MIND
OA, a moral imperative and a rule

National and international institutions and funding organizations support OA to research information and data

Issue policies and recommendations with varying embargo periods, as from 2000

- PLOS
- NIH
- European Commission
- Wellcome trust
- Telethon
- Italian research institutes
- The European Commission

Not only publications → data
FROM OPEN ACCESS TO RESEARCH PUBLICATION TO OPEN DATA

OA Declarations
OA Policies
OA Mandates

OPEN DATA

OPEN SCIENCE

4th International Summer School on Rare Diseases
OA is a philosophy and not an archive

**OA routes**

OA journals (gold)

Digital archives (green)

CREATE AWARENESS among all stakeholders

**Directory of Open Access Journals (DOAJ)**

>9000 journals

Latest News

Policy updates - open access statement

Open Access Statement Until recently, DOAJ was not an open access journal. All articles are now open access. This means that anyone can read, download, copy, distribute, and build on the articles without asking permission from the publisher or the author. The articles are also freely available to the public, and the copyright holder retains the copyright.

OA is a philosophy and not an archive

DoA: Journal of Open Access Journals (DOAJ)

2600 listings

CREATE AWARENESS among all stakeholders
Publisher copyright policies & self-archiving

Search

- Journal titles or ISSNs
- Publisher names
- Exact title
- starts with
- contains
- ISSN

Advanced Search  Search  Reset

Use this site to find a summary of permissions that are normally given as part of each publisher’s copyright transfer agreement.

Check what the publisher allows to do with your paper
Share your research results with the world is key to the progress of your discipline and career. But with so many publications, how can you be sure you can trust a particular journal? Follow this check list to make sure you choose trusted journals for your research.

https://vimeo.com/151882443
The article of the future

It shows the advantages of enriched articles including supplementary information and interactive content.

It provides true immersion in the contest of the subject matter.

Data are linked to databases providing the most updated information.

It proves a positive correlation among data sharing, citations and impact.

The Article of the Future is now live! Have you experienced it?

Recalling from the Article of the Future project innovations, we are now able to announce the SciVerse ScienceDirect redesigned article page, with a new layout including a navigational pane and an optimized reading middle pane.

The Article of the Future project: an ongoing initiative aiming to revolutionize the traditional format of the academic paper in regard to three key elements: presentation, content and context.

Learn what we are doing and why by viewing the video below.
Challenges of dissemination

- Guidelines
- Peer review
- Impact factor
- Open access and open science

Would you like to publish more? Whose task is this?
GENERAL ADVICE for researchers
To get your article published

SELECT the right OA journal (DOAJ)
READ the Instructions to authors

- Plan your work in advance
- Select the best type of communication (target, objective, context)
- Consider time and resources available

- Define authorship & responsibilities (collaborators)
- Consider previous work (bibliographic search)
- Follow instructions to authors (if available)
- Produce a first draft

- Revise the draft, seek advice, share, test the product
- Submit for publication (peer review process)
- Approve final draft

- Disseminate and Share (online, print, social, talks, links, repositories, etc.)
Ethical considerations applying to scientific publications also apply to research data

Discussion
You need to publish
You need to share data

WHY NOT?

A survey on researchers’ attitude towards data sharing will be launched in Italy, following *Researchers and their data. Results of an Austrian survey. Report 2015* [https://blogs.openaire.eu/?p=619](https://blogs.openaire.eu/?p=619)

The topics of the survey were:
- Data types and formats;
- Data archiving, backup and loss;
- Ethical and legal aspects;
- Accessibility and subsequent use;
- Infrastructure and services.
Glossary

A major difficulty in any newly emerging discipline is the lack of a precise and definitive taxonomy of terms. Different communities use the same terms in different ways which can make effective communication problematic. RDC is primarily, but not exclusively focused on data that are digital.

There are occasions when analogue forms of data are also important to research. The following working definitions are those employed by RDC and are intended be used as a practical tool. These definitions may not necessarily achieve widespread consensus among the wide ranging communities that use and produce research data. They are offered here as a mechanism to avoid potential ambiguities in the body of RDC documents rather than as a definitive gloss. This should be considered to be a living document that will be updated and amended as required. [Adapted from Digital Preservation Coalition]

Terms and Definitions
About Aisa

AISA is a non-profit organization that undertakes to advance open access to knowledge.

The mission of AISA is to:

1. disseminate a culture of Open Science;
2. publish studies on the implementation of Open Science principles;
3. provide staff training programs to promote Open Science practices in research performing organizations (universities and research centres) which have embraced the OA principles;
4. engage international cooperation through networking with legal entities involved in the promotion of Open Science;
5. promote participation in international research projects and grant applications linked to the association's mission;
6. raise awareness among decision makers, and in particular Italian and European legislators, to further the promotion of Open Science in research assessment and intellectual property policies.

On June 18th, 2015, the first Board of Directors was elected during the general assembly chaired by Roberto Caso.

The first Aisa annual conference took place on 22nd-23rd October 2015 in Pisa. All the conference slides may be downloaded from the "Archivio Giuliano Marini".

Promoting the culture of open science

Recent posts

- First international workshop on reproducible Science- Hannover, Sept. 9th, 2016
- National OpenAIRE Workshop, Rome May 2016: presentations and videos available
- Webinar on OpenAIRE call for proposals APC-free Open Access Journals and platforms 12th 2016
- White paper: Open Science in a Digital Republic
- Opening the Black Box of Scholarly Communication: A Public Data Infrastructure for Flows in Academic Publishing

Popular Posts

- National OpenAIRE Workshop, Rome May 2016: presentations and videos available (1-
there is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have put themselves at risk.

Many funders around the world —foundations, government agencies, and industry — now mandate data sharing.
EASE statement on data sharing 4 April 2016

The European Association of Science Editors (EASE) supports all initiatives on data sharing that are: (i) based on good editorial practice; (ii) take data protection issues into account; and (iii) consider publication ethical codes of conduct. As such, EASE is in agreement with the recently proposed requirement from the International Committee of Medical Journal Editors (ICMJE) that makes sharing of clinical trial data mandatory for manuscript acceptance by its member journals (1).

EASE believes that the transparency of clinical trial conduct and outcomes is paramount to the public’s trust in science. Transparency promotes well-informed use of medical interventions, permits verification of research, and helps to avoid duplication (thus reducing research waste). Reuse of shared data enables generation of new knowledge both for current clinical practice and for future research. Thus data sharing has the potential to affect the health both of individuals and the population.

The post-grant Open Access Pilot covers OA Article Processing Charges (APCs) for FP7 projects up to two years after they end.

Funded publications must be peer-reviewed and be made available under a CC-BY licence where possible.
Commission launches pilot to open up publicly funded research data

Valuable information produced by researchers in many EU-funded projects will be shared freely as a result of a Pilot on Open Research Data in Horizon 2020. Researchers in projects participating in the pilot are asked to make the underlying data needed to validate the results presented in scientific publications and other scientific information available for use by other researchers, innovative industries and citizens. This will lead to better and more efficient science and improved transparency for citizens and society. It will also contribute to economic growth through open innovation. For 2014-2015, topic areas participating in the Open Research Data Pilot will receive funding of around €3 billion.

The Commission recognises that research data is as important as publications. It therefore announced in 2012 that it would experiment with open access to research data (see IP/12/790). The Pilot on Open Research Data in Horizon 2020 does for scientific information what the Open Data Strategy does for public sector information: it aims to improve and maximise access to and re-use of research data generated by projects for the benefit of society and the economy.
International Rare Disease Research Consortium

IRDRC POLICIES AND GUIDELINES
Researchers are expected to comply with the following:

- RD research to be collaborative
- Quick release of data for public use
- Data deposited in public databases
- Contribution to a well-curated list of RD
- Interoperability and harmonization of data repositories
- Sharing of data while respecting IP
- Publication of negative results
- Involvement of patients in all relevant aspects of research
- Acknowledgement of the use of infrastructures: biobanks and registries

4th International Summer School on Rare Diseases,
H2020 Programme
Guidelines on FAIR
Data Management in Horizon 2020
July 2016

Data Management plan for research data to be FAIR:
**Findable, Accessible, Interoperable and Reusable**
to ensure it is soundly managed.

Good research **data management** is not a goal in itself, but rather the **key conduit** leading to knowledge discovery and **innovation**, and to subsequent data and knowledge **integration** and **reuse**.
Takes into account the need to balance openness and

- protection of scientific information,
- commercialisation and
- Intellectual Property Rights (IPR)
- privacy concerns
- security
- data management
- preservation.

Encourages sound data management as an essential part of research best practice.

Data Management Plan (DMP) is a deliverable to be submitted at month 6
A template is available

“as open as possible, as closed as necessary"

Initially only selected areas from 2017 → all thematic areas
How to recognize the value and impact of data sets?

Biobanks as an example

Standard citations of bioresources in journal articles to evaluate their impact
A multidisciplinary project involving researchers and editors
→ COBRA guidelines
The neglected role of research biobanks

In scientific publications, biobanks are:

- Not cited at all
- Cited in a heterogeneous way
- Not cited in a standardized way
- Difficult to retrieve

**What is needed**

- Sensitize journal editors to BRIF issues
- Standardize citations in journal articles
- Modify editorial guidelines
- Inform the scientific community about the relevance of this issue
A GUIDELINE TO STANDARDIZE CITATION OF BIORESOURCES

Publication of the CoBRA guideline, BMC Medicine 2015

Guideline

Developing a guideline to standardize the citation of bioresources in journal articles

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For all author emails, please log on.


Highly accessed article

Share and take advantage from recognition of their use.
a guideline to standardize citation of bioresources: a contribution towards reducing waste in research

Paola da Costa (1), Eliana Bravo (2), Alessia Calvello (3), Anna Cambon-Thomsen (4), Laurence Albailer (5), Rodolfo Napoli (5), Anna Maria Rossi (5)

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Background
A guideline for standard citation of bioresources has been recently published (BMC Medicine, 2015).
Bioresources are collections of biological samples with associated medical, epidemiological, biological or social data (biobanks), as well as collections of data of biological origin (databases) or bioinformatics tools.

They are drivers of innovation and scientific progress and their sharing is a priority for biomedical research; yet, the limited documentation of the efforts required to establish, maintain and share them is an obstacle for impact assessment, often leading to waste.

Objective
A collaboration between journal editors, supported by the EASE and scientists in different fields led to the development of the CoBRA (Citation of Bioresources in Journal Articles) guidelines introducing for the first time a standardized citation of bioresources in scientific publications. CoBRA was elaborated within the BIHR (Biobank or Research Impact Factor) initiative, aiming at improving transparent reporting of bio resources-based research and promoting reproducibility. CoBRA will contribute to measure bioresources use and impact, considering the huge investments required to organise and maintain such valuable collections.

Methods
CoBRA sample citations will be provided as well as recommendations for journal editors. The rationale of the guideline and how it can impact on research evaluation and reduce waste will be discussed.

CoBRA guidelines
is included in:
• EASE guidelines
  for authors
• Equator network

Conclusions
CoBRA helps to create awareness among different stakeholders, researchers, editors, institutional partners, policy-makers, patients, donors with direct implications on bioresources investment and waste in research. Editors can play a crucial role for CoBRA application, but the widespread use of the guideline is still a challenge.

To know more...
(CoBRA guidelines)

Reducing waste in research

Health professionals

Patient

Policy makers

Researchers

Donors

Editors

Reducing waste in research
Many items apply to all data sharing initiatives

**Impact of CoBRA implementation**

- Standardize the bioresource citation
- Tool to recognize work of setting up and maintaining valid bioresource
- Favor literature tracking of bioresource use for stakeholder, scientists, patients, donors
- Increase visibility of researcher, institution, sponsor
- Base for development of measureable index that impact on that value for career development (bibliometric issues) and economic sustainability
- Incentivize citation and sharing
- Decrease the waste in science (human and financial resources)
Like all patients, what I want most from clinical research is treatments that work, not ones that merely look good on paper. As The BMJ has pointed out, patients are often faced with over-hyped treatments and an incomplete research base biased towards positive results.

These biases arise partly because of “publish or perish” pressure on researchers. By contrast, patients’ only concern is to establish what really works: their interests are directly aligned with those of good science and sound medicine.

So, well informed patients should have the right to query research findings, and researchers should be willing to engage constructively and transparently with patients who challenge them.
Still some work to be done…..
Data sharing: main advantages

- Re-analysis of data to verify results, independent scrutiny
- New discoveries in old data sets
- Long-term preservation, data integrity
- Re-collection of data minimized, use of resources optimized
- Replication studies as training tools
BUT…. Empty archives

Data lying on personal hard drives and CD. Researchers not annotating datasets with rich metadata and losing access and understanding of the original dataset.
### General User Reporting System

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<th>Number of enrolled cases (last report)</th>
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<td>European HD REGISTRY</td>
<td>Registry 13000 (04.06.2015)</td>
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<td>Biobank 4317 (20.04.2015)</td>
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<td>Registry 4159 (30.05.2014)</td>
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<td>American Partnership for Eosinophilic Disorders</td>
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<td><img src="logo14.png" alt="Logo" /></td>
<td>Spanish patient registry of hereditary retinal dystrophy</td>
<td>Registry 3278 (29.06.2015)</td>
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... What would limit your participation? What would convince you?
Data sharing by scientists: practices and perceptions.
Tenopir et al. Plos One 2011;6(6):e21101

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<th>Reason</th>
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doi:10.1371/journal.pone.0021101.t012

... Are we missing any reason?
Who Shares? Who Doesn’t? Factors Associated with Openly Archiving Raw Research Data

Heather A. Piwowar*"n

Analysis on 124 diverse bibliometric attributes of the data creation articles revealed 15 factors describing authorship, funding, institution, publication, and domain environments. In multivariate regression, authors were most likely to share data if they had prior experience sharing or reusing data, if their study was published in an open access journal or a journal with a relatively strong data sharing policy, or if the study was funded by a large number of NIH grants. Authors of studies on cancer and human subjects were least likely to make their datasets available. These results suggest research data sharing levels are still low and increasing only slowly, and data is least available in areas where it could make the biggest impact.

Privacy: main barrier to data sharing?
An age of collaboration: global data and global research
UDNI Countries

Australia
Austria
Bulgaria
Canada
Hungary
India
Italy
Japan
Korea
Spain
Sweden
USA
Mission: accelerate progress in human health by helping to establish a common Framework of harmonized approaches to enable effective and responsible sharing of genomic and clinical data and to catalyze data sharing projects that drive and demonstrate the value of data sharing.
Much research data about people—even sensitive data—can be shared ethically and legally if researchers employ:

• strategies of informed consent
• anonymisation
• controlling access to data
Broad consent

• At the time of data/samples collection, their future specific use may still not be foreseen
• In broad consent, an individual gives consent to widely specified research (cancer research, RD research), which allows for many future uses of tissue and data
• Broad time frame
• Broad geographical frame

... Would you give broad consent for the use of your tissues/data? What the pros and cons?
• Proper on-going ethical and legal oversight are in place (e.g. approval by a research ethics committees for new projects).
• There is a right to withdraw (?)
• There are mechanisms to update research participants on the use of their data/samples.
Dynamic Consent is a new approach for engaging individuals about the use of their personal information. It is also an interactive personalized interface that allows participants to engage as much or as little as they choose and to alter their consent choices in real time.

What makes Dynamic Consent ‘dynamic’?

- It allows the same samples/information to be (re)used with the knowledge and consent of the individual.
- It enables individuals to give and revoke consent in response to their changing circumstances.
- It allows people to be approached for different kinds of research or to obtain their opinions as new research projects are started and new ethical questions arise.
- Consent preferences can be modified over time.

... Would you like to be updated on the use of your tissues/samples? What the pros and cons?
The problem with old collections

Did the patient consent? Is the consent complete?

NO

Did the patient actively refuse an option

YES

Ask REC for permission to re-contact

PERMISSION GRANTED

NO

Did the original consent exclude something that you now want to do?
Are core elements missing?

YES

Re-contact patient for new consent or re-consent

NOT POSSIBLE

NO

Is it legal to ask for a waiver?

YES

Not possible to proceed

Ask Ethical board for permission to use samples and data in new project/sharing or other use
Anonymisation... The right solution?

- De-identification and re-identification of individual data
- Genetic information is shared among a same family or group

... Is anonymisation the right solution? What the pros and cons?
Governance framework

• Good governance underpins a system of data sharing that depends on trust
• Federated systems (registry doesn’t lose control of data)
• From “ownership” to “custodianship”
• Controlled access by: Accreditation of researchers; Unique identifiers for researchers; Data Access Committees; Research Ethics Committees; Data Access agreements.
Data access/transfer agreements

- Data Transfer Agreement (DTA)/Material Transfer Agreement (MTA): DTAs and MTAs should always be used to govern data/material transfer between parties.
- DTAs and MTAs are legal contracts that help ensure that the parties signing the agreement will comply with a set of rules defined by the involved parties. These documents state the scope of the use of data or bio-specimens, the limits posed by the informed consent used for the original collection, special limitations, duration of sharing and use, and other special conditions including donors’ expectations, etc.
Data access agreements

• Access agreements must be drafted clearly, so that researchers and their institutions are aware not only of their obligations, but also that “the border between acceptable and unacceptable conduct be clearly delineated and predictable.

• Explicit sanctions are important in order to respond effectively to any breach. These sanctions must be balanced—harsh enough to deter abuse by researchers and yet not to discourage access.
EUROPEAN COMMISSION

COM(2012) 11 final
2012/0011 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)

Coming into effect Spring 2018
Same rules for all EU Members
Article 9: Processing of special categories of personal data

1. The processing of personal data, (...) genetic data or data concerning health or sex life (...) shall be prohibited.

2. Paragraph 1 shall not apply where:
   (a) the data subject has given consent to the processing of those personal data,
   (h) processing of data concerning health is necessary for health purposes and subject to the conditions and safeguards referred to in Article 81; or
   (i) processing is necessary for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Article 83;
What’s new for citizens

A "right to be forgotten": When an individual no longer wants her/his data to be processed (...) the data will be deleted.

Easier access to one's data: Individuals will have more information on how their data is processed and this information should be available in a clear and understandable way. A right to data portability will make it easier for individuals to transmit personal data between service providers.

The right to know when one's data has been hacked: Companies and organisations must notify the national supervisory authority of data breaches and communicate to the data subject all high risk breaches as soon as possible so that users can take appropriate measures.
What’s new for citizens

Data protection by design and by default: Data protection safeguards will be built into products and services from the earliest stage of development, and privacy-friendly default settings will be the norm.

Stronger enforcement of the rules: data protection authorities will be able to fine companies who do not comply with EU rules up to 4% of their global annual turnover.
What’s new for Research

More “relaxed” towards secondary uses

Recital 33: It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research.
What’s new for Research

• More “relaxed” towards secondary uses

**Recital (50):** The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is *compatible* with the purposes for which the personal data were initially collected.

**Art 5:1(b) further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall,** in accordance with Article 89(1), *not be considered to be incompatible with the initial purposes* (‘purpose limitation’);
CHAPTER III - Rights of the data subject

Article 12: Transparent information, communication and modalities for the exercise of the rights of the data subject

1. The controller shall take appropriate measures to provide any information (...) relating to processing to the data subject in a concise, transparent, intelligible and easily accessible form, using clear and plain language(...)
Content of the information (Article 13)

• controller’s identity and contact information
• intended purposes of the processing activities
• possibility that the data will be transferred to another entity or to a third country where applicable
• data subject’s rights to access, rectification, erasure and to object to processing
• period for which the personal data will be stored, or the criteria used to determine that period.
Article 14: Information to be provided where personal data have not been obtained from the data subject

• An updated notice should be provided where a controller intends to further process data for a different purpose, including for research. Under Article 13(3), the subsequent notice must include both the new research purpose and the elements laid out in Article 13(2), which mainly concern the data subject’s rights with regard to her data.
Article 14: Information to be provided where personal data have not been obtained from the data subject

- a researcher may be *exempt from the notice requirement* if she received the personal data from someone other than the data subject, such as where the data came from a publicly available source. Article 14 exempts controllers in these circumstances, if “the provision of such information proves impossible or would involve a disproportionate effort,” which "could in particular be the case” in the research context.
Exemption to notify (Article 14(5)(b)).

- A researcher also may claim exemption if providing notice would be “likely to render impossible or seriously impair the achievement of the [research] objectives,” provided there are appropriate safeguards in place, “including making the information publicly available”
Exemption form the right to erasure and right to object

- The Regulation exempts research from the right to erasure if it is “likely to render impossible or seriously impair the achievement of the [research] objectives” (Article 17(3)(d)).

- A researcher may override a data subject’s objection to processing if “the processing is necessary for the performance of a task carried out for reasons of public interest” (Article 21(6)).
Transferring personal data to third countries for research purposes permitted if:

The country offers an “adequate level of protection” as determined by the European Commission (Article 45(1)).

Controller has implemented specific safeguards, including Binding Corporate Rules and standard contractual clauses.

Data subject has provided explicit consent after being informed of the risks related to the transfer (Article 46(2); Article 49(1)(a)).
Looking forward....