INCLIVA | VLC
Instituto de Investigación Sanitaria

INSTITUTIONAL POLICY ON

OPEN SCIENCE

Version 1, March 2025

1. Introduction

Open science has emerged as a global paradigm supported by numerous international organisations, including UNESCO, the Organisation for Economic Co-operation and Development (OECD), and the European Commission. These organisations promote open science as a means of making scientific research more accessible, inclusive and collaborative, with the aim of accelerating the advancement of knowledge and maximising its impact on society.

UNESCO, for example, issued its Recommendation on Open Science in 2021, emphasising the importance of sharing scientific results to strengthen science as a global public good. Similarly, the European Commission has implemented policies that encourage the adoption of open science practices to ensure that the benefits of research are widely distributed and that research is more efficient and reproducible. Directive (EU) 2019/1024 of the European Parliament and of the Council on open data and the re-use of public sector information establishes, in recitals 27 and 28 as well as in Article 10, the legal obligation to make publicly available data from publicly funded research. This Directive promotes the accessibility and reusability of data, fostering transparency and economic and social development through the free circulation of knowledge.

In Spain, the Law on Science, Technology and Innovation, amended by Law 17/2022, emphasises the importance of open science in Article 37. This legislation stipulates that knowledge generated through publicly funded research must be made available to society openly and free of charge, thereby promoting transparency, collaboration and efficiency in the use of resources.

The principles of open science include open access to scientific publications and data, the openness of methodologies and evaluation processes, the inclusive participation of diverse social actors in research, and dialogue with other knowledge systems. These principles not only promote the democratisation of knowledge but also enable global challenges such as poverty, health crises, climate change and biodiversity loss to be addressed more efficiently.

Recognising the importance of these principles and the need to align with international best practices, IIS INCLIVA is committed to adopting and promoting open science in all its research activities. This policy aims to establish guidelines and responsibilities to ensure that the research carried out in our accredited groups is transparent, accessible and conducted in collaboration with the global scientific community and society at large, thereby enhancing the scientific quality and social impact of our work. Thus, this policy is designed to align our research practices with international and national open science

standards, ensuring that our work contributes significantly to social well-being and global scientific development, whilst respecting data protection regulations and the open access obligations established by European and Spanish legislation.

2. Scope

This policy applies to research carried out by the accredited groups that make up the INCLIVA Health Research Institute.

3. Objectives

The implementation of an Open Science policy at the INCLIVA Health Research Institute is aimed at the following objectives:

- Improving Scientific Quality: Promoting transparency in methodology and access to data to increase the reproducibility and reliability of our research results.

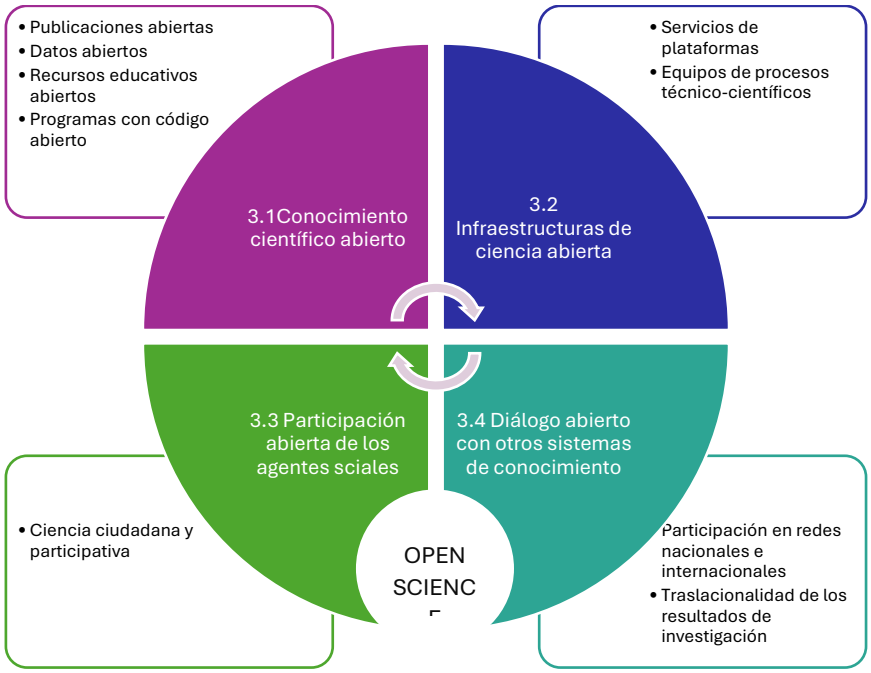
- Maximising social impact: Ensuring that the knowledge generated at the Institute is available for use by other researchers, healthcare professionals, policymakers and the general public, thereby contributing to the improvement of public health and well-being.

- Fostering Global Collaboration: Facilitating international and multidisciplinary cooperation through open access and the sharing of knowledge and resources.

- Accelerate Innovation: Reduce barriers to access to scientific knowledge to enable faster and more effective innovation in biomedical research.

3. Principles of Open Science

In 2021, the General Conference of the United Nations Educational, Scientific and Cultural Organisation (UNESCO) published the document “UNESCO Recommendation on Open Science”, which sets out the principles and guidelines that should govern scientific activity in general. Whilst the implementation and development of this document is the responsibility of bodies that set scientific policy at the na r international levels, specific actions relevant to research activity have been identified to ensure compliance with the principles proposed in this document. Accordingly, the actions to be undertaken at the IIS INCLIVA to comply with the principles of open science, as set out below, have been established.



1. Figure adapted from the diagram of Fundamental Pillars of the 'UNESCO Recommendation on Open Science' (2021).

3.1 Open scientific knowledge

3.1.1 Open Access to Publications: All research results managed by the Institute must be published in open-access journals or deposited in open-access repositories, ensuring they are available immediately or within the shortest possible timeframe.

A budget allocation will be set aside to fund open access publication for early-career researchers.

3.1.2 Open Research Data: Data generated from research carried out by INCLIVA research groups, which receive public funding, must be managed in such a way that they are accessible and reusable[1] , and in all cases in accordance with applicable ethical and legal regulations. Standardised, recognised repositories and open licences are used to facilitate their use by third parties. Support will be provided for the development of research data management plans.

[1] Formats that maximise interoperability should be used. Further information on this subject can be found at the following links:
https://opendatahandbook.org/guide/en/appendices/file-formats/
https://ukdataservice.ac.uk/learning-hub/research-data-management/format-your-data/recommended-formats/

Research data must be named and managed in accordance with applicable international best practices and must use standardised vocabulary and terminology[2] .

Where necessary, prior to the publication of data, an anonymisation process will be carried out[3] .

3.1.3 Open Educational Resources: Institutional training programmes for research staff must be made available to other entities within the biomedical or research sector and to individuals who may potentially conduct health research.

3.1.4 Open Source Software[4] : All software developed in the context of our research must be made available under open licences, allowing for its review, improvement and reuse by the scientific community and other interested users.

3.2 Open Science Infrastructures

3.2.1 Virtual infrastructure: All IIS INCLIVA research support services (Bioinformatics, Biostatistics, Integracloud, Data Science Office, management and support units) are available on a not-for-profit basis to support research activities.

3**.2.2 Physical infrastructure:** All services provided through the use of large-scale scientific equipment to which IIS INCLIVA has access are made available on a not-for-profit basis to support research activities.

3.3 Open participation of social stakeholders

3.3.1 Citizen Science and Public Participation: The public must be included in research processes through citizen science activities, improving public understanding of science and ensuring that our research responds to social needs.

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[2] The following medical terminology standards may be used, for example:
• ICD-10 for the identification of diseases and health problems
• LOINC for the identification of measurements, observations and healthcare documentation
• RxNorm for identifying medicines or drugs
• SNOMED-CT for the identification of clinical terminology
• MeSH for medical science descriptors
• Other classifications:
http://www.who.int/classifications/network/en/
http://www.dcc.ac.uk/resources/subject-areas/biology

[3] Data anonymisation may be carried out by the research team using tools such as https://amnesia.openaire.eu/, by the INCLIVA Data Science Office, or by a specialist third party.

[4] This does not apply to software generated under collaboration agreements, licences or using third-party property, nor to software that the institutional strategy requires to be protected for subsequent applications or commercial exploitation.

3.4 Open dialogue with other knowledge systems

3.4.1 Open dialogue with other knowledge systems: INCLIVA will actively promote its participation in the research ecosystem of the Carlos III Health Institute and in other national and international research networks.

3.4.2 Translational application of research results: The ultimate aim of the research will be its translational application to areas of greatest impact for the benefit of citizens and the general population, such as in the fields of clinical practice or health prevention and maintenance.

4. Responsibilities

- Management / Scientific Directorate: They shall ensure the availability of the necessary resources for the implementation of this policy and shall promote the necessary actions for its compliance in the research carried out within the IIS INCLIVA.

- **Principal Investigators of INCLIVA's accredited R&D&I groups**. They are responsible for adhering to the principles of open science, by appropriately planning data management and deposit, choosing open-access publication channels, and participating in open science activities. They must participate in training activities relating to open science. The Principal Investigator may delegate this responsibility to a member of the group.

- Research Support Units: These will provide technical and administrative assistance to implement this policy, including training in open science and the dissemination of science to the public.

- Data Science Office: This office will provide technical assistance and support for the anonymisation of research data prior to its open dissemination.

- Ethics Committee: This committee will ensure that open science practices comply with ethical and legal regulations, particularly those relating to the protection of personal data and confidentiality.

5. Specific implementation guidelines

5.1 Training and Awareness-raising: Information about the publication of this policy will be disseminated through institutional channels, ensuring that all relevant groups are made aware of it. Activities to train researchers in the use of open science tools and practices will be included as part of the training plan.

5.2 Resources and means: Mechanisms will be implemented to ensure the availability and accessibility of technical resources (specialised support and advice) and scientific and technological infrastructure for all research staff. Funding will be provided to early-career researchers for the open publication of their work.

5.3 Sustainability: Within a maximum of two years following the publication of this policy, institutional procedures will be documented to ensure the implementation and maintenance of all routine or permanent institutional actions undertaken for the purpose of its execution.

5.4 Recognition and Reward: INCLIVA-accredited groups that actively promote and/or effectively implement the principles of open science will be recognised. This effort will be taken into account in the evaluation of their scientific and research performance.

5.5 Compliance Assessment: Researchers must document their open science practices in progress reports and research proposals. Compliance with this policy will be assessed periodically using indicators[5] , with action taken should any of these indicators show deviations.

6. Exceptions and Special Considerations

- Exceptions to the publication of data and results will be permitted where justified on the grounds of intellectual property protection, confidentiality, or ethical and legal regulations.

- Exceptions must be approved by the CEIM before a decision is made not to disclose data or results.

- Exceptions to the publication of open-source software will be permitted where third parties are involved in its development or where there is an institutional directive or strategy requiring its protection.

[5] Annex I of this Policy contains the indicators used to monitor its implementation.

7. Monitoring

INCLIVA will establish an open science committee responsible for overseeing the implementation of this policy, evaluating its impact and promoting continuous improvements. This committee will report annually to the institution's governing bodies on the progress of adopting open science practices and will propose any necessary adjustments to consolidate them.

The committee will include staff from the fields of leadership, management, research and other research stakeholders.

The committee will carry out the following actions to monitor the implementation of this policy:

- Request, from each responsible party, the necessary information regarding the implementation of the open science policy at INCLIVA: dissemination and communication activities; support and advice provided; published internal grants; the incorporation of open science indicators into research group evaluation processes; and the measurement of indicators linked to the open science policy.
- Prepare a report, based on the evaluation of all the information received, to assess the extent to which open science has been implemented at the Institute.
- Identify aspects that should be removed, modified or included in the open science policy document, in order to bring it into line with INCLIVA's reality and interests in this field of activity.
- Submit the findings and conclusions of the evaluation report to the governing bodies, to provide an update on the status and implementation of this policy, and to approve its review and revision for the following financial year.

8. Review periods

This policy will be reviewed every five years, or sooner if deemed necessary, to adapt to changes in legislation, funding regulations or international best practices in open science.

9. Approval and Entry into Force

This policy was **drawn up** by INCLIVA's Quality and Data Protection Unit, **reviewed** by the Deputy Scientific Director and by the INCLIVA Foundation's Internal Scientific Committee

at a meeting on 25 March 2025. **It was** finally **approved** by the Governing Board, thereby coming into force on 31 March 2025.

Annex I - Indicators

Ref	Principle	Indicator	Indicator calculation	Yields	Expected value	Correspondence with other indicators
3.1.1	Open access publications	Percentage of publications resulting from publicly funded projects that have been published in Open Access journals	(No. of publications in OA media of results from publicly funded projects / total no. of publications of results from publicly funded projects) * 100.	Scientific output	100%	GTE 2024 --> 2.3.4.2
3.1.2	Open data	Percentage of research data from publicly funded projects resulting from open calls for proposals, following the FAIR principles (Findable, Accessible, Interoperable and Reusable), available openly in standardised open data repositories recognised within the discipline.	(Research data from publicly funded projects available in repositories / total research data from publicly funded projects) * 100	Quality	75%	GTE 2024 --> 2.3.4.3
3.1.3	Open educational resources	Number of training activities relating to open science carried out during the year	Number of training activities relating to open science carried out during the year	Training	4	
3.2.1	Virtual infrastructure	Number of virtual platforms	Number of virtual platforms offered to researchers	Platforms	2	
		Number of services provided by virtual platforms	Number of services provided by virtual service platforms during the year	Platforms	280	

3.2.2	Physical infrastructure	Number of physical platforms	Number of physical platforms offered to researchers	Platforms	6	
		Number of services provided by physical platforms	Number of services provided by physical service platforms during the year	Platforms	220	
3.3.1	Open participation of social partners	Outreach activities carried out by the IIS aimed at citizens from specific communities or target groups	Number of outreach activities aimed at non-scientific target groups to communicate the results of research projects	General Secretariat	7	
		Number of visitors to INCLIVA's facilities during outreach activities	Number of people visiting the IIS INCLIVA facilities to learn about the activities carried out there	Training	415	
		Percentage of projects (ISCiii criterion) generated with public participation	(Number of R&D&I projects initiated in accredited groups in which non-scientific stakeholders have actively participated in their design and/or in decision-making during their implementation, in the year under review / Number of projects initiated during the year in accredited groups) * 100	National projects / International projects	30% 2025 50% 2026 75% 2027 100% 2028	EvaGroups N4 Sum GTE 2024 --> 3.2.3.3
3.4.1	Interoperability with other systems	Number of networks in which INCLIVA is integrated as at the last day of the year	Number of legally recognised cooperative research networks or consortia, both national and international, in which INCLIVA is formally integrated	Scientific Management	At least 8 national and 3 international	GTE2024 --> 2.2.1.5, 2.2.1.6
3.4.2	Translational research	Number of clinical practice guidelines published	Number of clinical practice guidelines in indexed journals, published in the year	Scientific output	Minimum 12	EvaGroups E1 sum

		Number of results transferred to clinical practice in the year under review	Number of results transferred to clinical practice in the year under review	Innovation	Minimum 4/year	EvaGroups F1 sum
5.1	IMPLEMENTATION - Awareness-raising	Number of activities carried out to promote the Open Science policy	No. of activities carried out to promote the Open Science policy	Quality	5	
		% of researchers to whom the Open Science Policy has been effectively communicated	(No. of researchers from affiliated groups who have been informed of the Open Science Policy / No. of researchers from affiliated groups) * 100	Quality	100%	
		% of groups in which at least one researcher has participated in the open science training sessions to which they were invited	(No. of affiliated groups in which at least one member has attended all open science training sessions held during the year / No. of affiliated groups) *100	Training	100%	
		% of compliance with the open science training plan	(No. of activities included in the training plan that are carried out / No. of activities included in the training plan) *100	Training	100%	
5.2	IMPLEMENTATION - Resources	Amount allocated to open access publishing	Amount of own funds actually used during the year for open access publishing	Financial management	€20,000 per year	
		Amount allocated to networks	Amount of own funds actually spent during the year on participation in research networks	Sub-budget	€10,000/year	

5.3	IMPLEMENTATION - Sustainability	% of actions taken to comply with the policy with an institutional PNT	Number of sub-sections under point 3 of the policy that have an institutional document (PNT, instruction, regulation, etc.) ensuring their standardised and continuous operation / Number of sub-sections under point 3 of the policy (9) * 100	Quality	100%
		Number of PNTs ensuring compliance with this policy	Number of procedures managed by the quality unit relating to compliance with the open science policy	Quality	3
5.4	IMPLEMENTATION - Reward	% of research group evaluation indicators relating to open science	(No. of indicators in the research group evaluation relating to open science / No. of indicators in the research group evaluation) *100	Quality	10% (5 out of 63)
5.5	IMPLEMENTATION - Evaluation	% of groups that have incorporated open science principles	(No. of research groups working with open science principles / No. of research groups) *100	Scientific output	30% 2025 50% 2026 75% 2027 100% 2028
		% of indicators within the expected range	(No. of indicators within the expected range / Total no. of indicators) *100	Quality	50%
		Number of open science committee meetings held during the year	Number of open science committee meetings held during the year	Quality	4 ordinary