D1.1 Publication Policy

PP-2-3-2016 – EU-VIORMED

European Study on Risk Factors in Mental Disorder and Forensic Care: a multicenter study

	WP1 – Management of the project
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Publishable Summary

Deliverable 1.1 “Publication Policy” represents a summary of the outcomes of the activities carried out in the context of WP1 “Project Management” of the EU-VIORMED.

The EU-VIORMED project will produce a diverse range of papers, with each having differing levels of contributions from different people involved in the project. It is not possible to produce a detailed plan, which can cover all eventualities in terms of authorship and acknowledgements. This paper sets out the principles, based upon which final decisions will be made.

The present document represent the framework of activities concerning the publication of project outcomes and results to be carried out in the context of WP3 “Dissemination”, and which will be annually reported in the project Periodic Reports (MD.1, due at M12, 24, and 36).

1. Terminology

‘**WP leader**’ refers to people officially in charge of project’s Work Packages, as defined in the project Grant Agreement. ‘**Principle Investigator**’ (PI) refers to the scientific leader of the partner institutions involved in the EU-VIORMED project. **‘Site**’ refers to partner institutions i.e. beneficiaries. ‘**Study site**’ refers to centres included the ‘EU-VIORMED study’ (i.e. forensic units, hospitals, universities, etc.).

2. Potential authors

EU-VIORMED Principle Investigators (PIs), research assistants (RA), related PhD candidates, EU-VIORMED study site leaders and/or key clinicians, and other individuals who have made a significant contribution to the project can be potential authors.

The EU-VIORMED PIs are listed below (Table 1). We have also listed ALL other individuals as part of the EU-VIORMED Consortium in Appendix 1. Depending on the nature and type of publication, individuals in the consortium may be co-authors, be acknowledged or not be mentioned at all in specific publications. The consortium simply reflects the wider group, which has contributed to the project. There is no guarantee that being listed in the consortium offers any certainty of authorship.

The composition of the EU-VIORMED Consortium will vary according to work package and the type of publication (Type I, II or III paper: see section 3). For example, the list of individuals in papers reporting the findings of the EU-VIORMED risk assessment study and case-control study (WP4 and WP5) will be extensive, as it will include EU-VIORMED study site leaders and/or key clinicians. On the other hand, publications linked with, for example, WP6 and WP7 will include a shorter list, as few individuals in the wider group will have contributed to the tasks linked with these work packages.

Table 1. EU-VIORMED PIs at partner institutions/beneficiaries (Invited to be co-authors on all Type I papers)

Acronym	Name	Institution	WP
01 IRCCS - FBF	**Giovanni de Girolamo**	Saint John of God Clinical Research Centre, Brescia, Italy	WP1
02 KCL	**Marco Picchioni**	Institute of Psychiatry, King's College London, London, UK	WP4
03 MANN	**Hans Joachim Salize** **Harald Dreßing**	Zentralinstitut fuer Seelischee Gesundheit	WP6
04 MUW	**Johannes Wancata**	Medizinsche Universitaet Wien	WP5
05 IPIN	**Janus Heitzman**	Instytut Psychiatrii I Neurologii	WP2
06 UDUS	**Heiner Fangerau**	Heinrich-heine-Universitaet Dusseldorf	-
07 EUFAMI	**Margaret Walker**	Europese Federatie van Familieverenigen van Psychiatrischzieke Personenivw	-
08 UNIMIB	**Giuseppe Carrà**	Università degli Studi di Milano-Bicocca	WP3

3. Principles of publication and authorship

- Delivery of the programme work must take priority over writing papers. Publications are important, but we need data on which to publish.
- Main research questions (Type I paper, below) will inform the first round of potential papers, which will be identified and documented in advance by the PIs (and other researchers).
- **Authorship** will be based on the principles stated in the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals of the International Committee of Medical Journal Editors (available at http://www.icmje.org/recommendations). This means that all PIs have the right to be offered authorship of the paper as long as they fulfill the following criteria:
  - Substantial contributions to the conception or design of the work; or the acquisition, analysis, and interpretation of data for the work; AND
  - Drafting the work or revising it critically for important intellectual content; AND
  - Final approval of the version to be published; AND
  - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

These criteria apply when discussing authorship of all products of the project.

- There will be three kinds of papers emerging from the project:
  - **Type I:** the main papers, related to the primary aim/task of an individual WP. A WP may have more than one aim, and lead to several papers. However, each WP should produce in principle at least one Type I paper.
  - **Type II:** further papers using main data sets from specific WPs exploring subsidiary hypotheses.
  - **Type III:** papers that explore questions of interest to individual members, or hypotheses not central to the primary objectives of the programme.
- Type I papers will have priority over Type II, and Type II over Type III.
- Main authors are defined as first, second and last author. First, second and last authors will do the main drafting of the paper and choose the corresponding author.
- For each Type I paper, the WP leader and the lead Research Assistant (RA) will be the main authors. It will be their responsibility to write and circulate the first draft.
- RAs will be encouraged to publish papers; first authorship of Type II and III papers will be their 'pay-back' for prioritising delivery of Type I papers. However PI may offer first authorship to an RA on Type I paper if they so wish.
- There will be two methods papers: one setting out the methods and procedures of the overall EU-VIORMED project (WP1 and WP 2) and one on the EU-VIORMED Clinical Study Protocol (WP4). All subsequent papers will refer to these papers for background methodological details. These papers will be submitted as soon as possible.
- The title and contents of all Type I papers will be discussed within the consortium and agreed in consensus manner ensuring that while Type I papers are of the highest possible quality, data usage does not prevent/encroach upon Type II and III papers from that WP.
- Once agreed, there will be clear timelines by which main authors have to produce the first draft for each Type I paper. Each Type I paper must include all relevant co-authors (see 'Authorship' above). EU-VIORMED PIs will be invited to be co-authors on all Type I papers. The WP leader for the paper will ensure that the names of all other relevant co-authors are included, consulting PIs of each partner institution. This should ideally happen before the first draft of the paper is written. Key authors will be listed in the by-line individually (PIs and other significant co-authors), others will be listed as part of the EU-VIORMED Consortium (see below).
- Type II and III papers which use data from all sites will also require discussion within the consortium and must include at least one co-author from each site. The manuscripts of Type II and III papers should be sent to all EU-VIORMED PIs.

- Type III papers may be discussed in smaller groups, especially if the data included are site-specific.
- For site-specific Type III papers linked with a WP specific task or the EU-VIORMED study, PIs can offer co-authorship to local key clinicians/academics who have contributed to data collection, analysis or any other local input.
- WP leaders can choose to delegate responsibility/authorship to another individual. This is their right and prerogative. However, the responsibility for delivery will lie with the WP leader.
- The key principle for authorship will be contribution (as described above).
- *Conflict of Interest declarations must be completed by each author.*
- Disputes on authorship will be resolved in an open, transparent, amicable and fair manner. The EU-VIORMED Principal Investigator (Giovanni de Girolamo) reserves the right to have the final say in a dispute that does not lend itself to resolution by negotiation.
- All publications will mention the EU-VIORMED Consortium, whereby individuals in the group are either co-authors or acknowledged. The latter will depend on the type of publication, and will have to be decided every time a manuscript is produced. Hence the composition of the Consortium will vary from paper to paper.

4. EU-VIORMED Consortium as group author

The International Committee of Medical Journal Editors recommends the following:

> *"When submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists, and clearly identify the group members who can take credit and responsibility for the work as authors. The by-line of the article identifies who is directly responsible for the manuscript, and MEDLINE lists as authors whichever names appear on the by-line. If the by-line includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the by-line clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators."*
>
> *"All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete conflict-of-interest disclosure forms*."

When individuals listed in the 'EU-VIORMED Consortium' are co-authors on a publication (see criteria in section 3), the following format will be used:

[names of main authors] **and** the EU-VIORMED Consortium

Consequently, a list of individuals and affiliations should be added to the manuscript before submission, clearly stating that these are co-authors on the publication, and activities undertaken by 'EU-VIORMED Consortium' should be specified in 'author contributions'.

5. EU-VIORMED Consortium as acknowledgements (and "non-author collaborators")

Contributors who meet fewer than all 4 of the above criteria for authorship (section 3) should not be listed as authors, but they should be acknowledged.

If individuals listed in the EU-VIORMED Consortium do not meet all criteria, such as in work package specific publications, then the EU-VIORMED Consortium should be acknowledged in the by-line in the following fashion:

- [names of main authors] **for** the EU-VIORMED Consortium

In these instances, individuals in the EU-VIORMED Consortium will be listed separately as collaborators (i.e. non-author contributors, usually at the end of the paper) and not be mentioned in 'author contributions'.

Publications produced as a result of work package specific tasks may result in other acknowledgements (e.g. List of country experts for WP1).

Every publication will acknowledge EU funding:

- "This [*insert appropriate description, e.g. report, publication, conference, infrastructure, equipment, insert type of result, etc.]* is part of the European Study on Risk Factors for Violence in Mental Disorder and Forensic Care: a multicentre project (EU-VIORMED) which has received funding from the European Union."
- This paper reflects only the author's views and the European Union is not liable for any use that may be made of the information contained therein."

6. PhDs associated with EU-VIORMED

All sites have been encouraged to have PhDs associated with EU-VIORMED project. Given that a PhD requires an individual candidate's independent intellectual input, PhD candidate **MUST** collect **ADDITIONAL** data to answer **ADDITIONAL** questions.

Additional research questions shall be firstly circulated within the EU-VIORMED group.

Papers arising from such work can be Type I, Type II or Type III papers, with the PI as the senior author and the PhD candidate the first author.

If the PhD does not include data from EU-VIORMED or from other sites, the site leader and the PhD candidate will have full rights over the data and do not have to consult the Consortium, although it is expected that they will.

7. The process of drafting a paper

- All paper proposals shall be reviewed by the EU-VIORMED PI and the Coordination Team and recorded on an online spreadsheet (to be set up and managed by the Coordination Team). The publication document will be reviewed periodically.
- Authorship of the writing of the paper (writing group) should be decided on at the time of proposing the paper.
- The lead author will draft the paper and then send the version to the authors identified as the writing group.
- The lead author will collate comments and make appropriate changes as relevant to the paper.
- The lead author has final say on the changes made.
- The second draft of the paper should then be sent out to all authors who must fulfil the Authorship criteria above to be included on the paper.
- PIs and other authors have the right to decline authorship if they wish.
- The lead author then collates comments again as before and completes a final version of the paper. This final version will be sent to all co-authors for their information and their final decision to be listed as co-author or not.
- The PI and the WP leader should have oversight of the paper prior to it being submitted to ensure that there are not any potential reputational issues for University departments or individual members of the project.

8. Legal matters related to publications

Prior notice of any planned publication (including papers, oral presentations, posters, etc.) shall be given to the other Parties concerned at least forty-five (45) days before the submission. Any objection to the planned publication shall be made in accordance with the GA in writing to the Project Coordinator and to any Party concerned within thirty (30) days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

An objection is justified if:

- the objecting Party's legitimate academic or commercial interests are compromised by the publication; or
- the protection of the objecting Party's Foreground or Background is adversely affected; or
- the proposed publication includes the Confidential Information of the objecting Party.

The objection has to include a precise request for necessary modifications.

If an objection has been raised, the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate actions are performed following the discussion. In all cases, delay in publications shall not exceed 90 days following notice of the publishing Party.

9. Publication of another Party's Foreground or Background

For the avoidance of doubt, a Party shall not publish Confidential Information, Foreground or Background of another Party, even if such Confidential Information, Foreground or Background is amalgamated with the Party's Foreground, without the other Party's prior written approval. For the avoidance of doubt, the mere absence of an objection according to point 5 is not considered as an approval.

10. Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense of any dissertation or thesis for a degree that includes their Confidential Information, Foreground or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

11. <u>Open Access (Addition to Grant Agreement – PP-2-3-2016)</u>

In addition to Article 22 of the EU-VIORMED Grant Agreement, beneficiaries shall deposit an electronic copy of the published version or the final manuscript accepted for publication of a scientific publication relating to foreground published before or after the final report in an institutional or subject-based repository at the moment of publication.

Beneficiaries are required to make their best efforts to ensure that this electronic copy becomes freely and electronically available to anyone through this repository:

- immediately if the scientific publication is published "open access", i.e. if an electronic version is also available free of charge via the publisher, or
- within 6 months of publication.

Appendix 1 – EU-VIORMED Consortium

The scientific/WP leaders of each partner institution will decide who from the following table will be included in the 'EU-VIORMED Consortium' list for each publication (in alphabetic order).

EU-VIORMED Consortium

Country/Site	Name (in alphabetic order)	Institution (Acronym)
01 IRCCS - FBF	• Chiara Barattieri di San Pietro • Viola Bulgari • Giovanni de Girolamo • Clarissa Ferrari • Ambra Macis	Saint John of God Clinical Research Center, Brescia, Italy
02 KCL	• Nigel Blackwood • Marco Picchioni	Institute of Psychiatry, King's College London, London, UK (KCL)
03 MANN	• Harald Dreßing • Andrea Giersiefen • Barbara Horten • Hans Joachim Salize	Zentralinstitut für Seelische Gesundheit
04 MUW	• Alexander Dvorak • Andreas Reisseger • Thomas Stompe • Annemarie Unger • Johannes Wancata • Andrea Giersiefen	Clinical Division of Social Psychiatry, Medical University of Vienna, Vienna, Austria
05 IPIN	• Pawel Gosek • Janus Heitzman • Inga Markiewicz • Marta Ozimkowicz • Marek Pacholski	Department of Forensic Psychiatry, Institute of Psychiatry and Neurology, Warsaw, Poland
06 UDUS	• Heiner Fangerau • Chantal Marazia • Vasilija Rolfes	Institut für Geschichte, Theorie und Ethik der Medizin Heinrich-Heine-Universität Düsseldorf
07 EUFAMI	• Margaret Walker • Spyros Zorbas	European Federation of Associations of Families of People with mental illness, Leuven, Belgium
08 UNIMIB	• Francesco Bartoli • Giuseppe Carrà • Cristina Crocamo	Department of Medicine and Surgery, University of Milano Bicocca, Italy