

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

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1. Identifying information.

2. The work under consideration for publication.

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4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

5. Relationships not covered above.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Domenico

2. Surname (Last Name)
Alvaro

3. Date
19-November-2020

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Marco Carbone

5. Manuscript Title
Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)
JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Shionogi	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Intercept Pharmaceuticals	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Aboca	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Vesta-Usa	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Dr. Alvaro reports personal fees from Shionogi, grants and personal fees from Intercept Pharmaceuticals, personal fees from Aboca, grants from Vesta-Usa, outside the submitted work; .

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Section 1. Identifying Information

1. Given Name (First Name)

Leonardo

2. Surname (Last Name)

Baiocchi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

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JHEPR-D-20-00216

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Dr. Baiocchi has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name)

Valentina

2. Surname (Last Name)

Bellia

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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1. Given Name (First Name)

Gaetano

2. Surname (Last Name)

Bertino

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco carbone

5. Manuscript Title

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6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Dr. Bertino has nothing to disclose.

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Roberto

2. Surname (Last Name)

Boldizzoni

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

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Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Vincenza

2. Surname (Last Name) Calvaruso

3. Date 19-November-2020

4. Are you the corresponding author? Yes No Corresponding Author's Name Marco Carbone

5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
AbbVie	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gilead	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Intercept Pharmaceutical	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MSD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

- Yes, the following relationships/conditions/circumstances are present (explain below):
- No other relationships/conditions/circumstances that present a potential conflict of interest

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Calvaruso reports personal fees from AbbVie, personal fees from Gilead, personal fees from Intercept Pharmaceutical, grants from MSD, outside the submitted work; .

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Mariarita

2. Surname (Last Name)

Cannavò

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Cannavò has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Marco

2. Surname (Last Name)

Carbone

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Intercept	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

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Section 6. Disclosure Statement

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Dr. Carbone reports personal fees from Intercept, outside the submitted work; .

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Silvia

2. Surname (Last Name)

Casella

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Casella has nothing to disclose.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Antonino

2. Surname (Last Name)

Castellaneta

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Dr. Castellaneta has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Nora	2. Surname (Last Name) Cazzagon	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Intercept Pharmaceuticals	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

- Yes, the following relationships/conditions/circumstances are present (explain below):
- No other relationships/conditions/circumstances that present a potential conflict of interest

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Section 6. Disclosure Statement

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Dr. Cazzagon reports personal fees from Intercept Pharmaceuticals, outside the submitted work; .

Evaluation and Feedback

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Luchino

2. Surname (Last Name)

Chessa

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest?

Yes

No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest?

Yes

No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work?

Yes

No

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Section 6. Disclosure Statement

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Dr. Chessa has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Ernesto

2. Surname (Last Name)

Claar

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Dr. Claar has nothing to disclose.

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Francesca

2. Surname (Last Name)
Colapietro

3. Date
19-November-2020

4. Are you the corresponding author? Yes No

Corresponding Author's Name
Marco Carbone

5. Manuscript Title
Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)
JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Colapietro has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Raffaele

2. Surname (Last Name)

Cozzolongo

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Cozzolongo has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Laura

2. Surname (Last Name)

Cristoferi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

5. Manuscript Title

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JHEPR-D-20-00216

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Daphne

2. Surname (Last Name)

D'Amato

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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Mother is working at Intercept Pharmaceuticals

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Dr. D'Amato reports Mother is working at Intercept Pharmaceuticals.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Maria

2. Surname (Last Name)

D'Antò

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Dr. D'Antò has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Elisabetta

2. Surname (Last Name)

Degasperi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Degasperi has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Antonio

2. Surname (Last Name)

De Vincentis

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

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Dr. De Vincentis has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Marco

2. Surname (Last Name)

Distefano

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Dr. Distefano has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Stefano	2. Surname (Last Name) Fagioli	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Gilead	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ABBvie	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MSD	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Intercept	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Novartis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Astellas	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Bayer	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Kedrion	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

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- No other relationships/conditions/circumstances that present a potential conflict of interest

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Section 6. Disclosure Statement

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Dr. Fagioli reports personal fees from Gilead, personal fees from ABBvie, personal fees from MSD, personal fees from Intercept, personal fees from Novartis, personal fees from Astellas, personal fees from Bayer, personal fees from Kedrion, outside the submitted work; .

Evaluation and Feedback

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Valentina

2. Surname (Last Name)

Feletti

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest?

Yes

No

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Are there any relevant conflicts of interest?

Yes

No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work?

Yes

No

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Dr. Feletti has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Annarosa

2. Surname (Last Name)

Floreani

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

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Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Floreani has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Rossana

2. Surname (Last Name)

Fontana

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Fontana has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Evelise

2. Surname (Last Name)

Frazzetto

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Are there any relevant conflicts of interest?

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Giovanni

2. Surname (Last Name)

Galati

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

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JHEPR-D-20-00216

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4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

5. Relationships not covered above.

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Alessio

2. Surname (Last Name)

Gerussi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Gerussi has nothing to disclose.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Giuseppe

2. Surname (Last Name)

Grassi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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No

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Dr. Grassi has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Pietro	2. Surname (Last Name) Invernizzi	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Intercept Pharmaceuticals	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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Dr. Invernizzi reports grants and personal fees from Intercept Pharmaceuticals, outside the submitted work.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Antonio	2. Surname (Last Name) Izzi	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

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Are there any relevant conflicts of interest? Yes No

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Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Izzi has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Sara

2. Surname (Last Name)
Labanca

3. Date
19-November-2020

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Marco Carbone

5. Manuscript Title
Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)
JHEPR-D-20-00216

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Intercept	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	speaker for Intercept

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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Dr. Labanca reports personal fees from Intercept , outside the submitted work; .

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Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Ana	2. Surname (Last Name) Lleo	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Intercept	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
AlfaSigma	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Takeda	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abbvie	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gilead	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Merk Sharp & Dohme	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

- Yes, the following relationships/conditions/circumstances are present (explain below):
- No other relationships/conditions/circumstances that present a potential conflict of interest

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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Lleo reports personal fees from Intercept, personal fees from AlfaSigma, personal fees from Takeda, personal fees from Abbvie, personal fees from Gilead, personal fees from Merk Sharp & Dohme, outside the submitted work; .

Evaluation and Feedback

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Francesco

2. Surname (Last Name)
Losito

3. Date
19-November-2020

4. Are you the corresponding author? Yes No

Corresponding Author's Name
Marco Carbone

5. Manuscript Title
Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)
JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Losito has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Federica	2. Surname (Last Name) Malinverno	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Malinverno has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Clara

2. Surname (Last Name)

Mancuso

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Section 4. Intellectual Property -- Patents & Copyrights

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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Section 6. Disclosure Statement

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Dr. Mancuso has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Giulia

2. Surname (Last Name)

Marconi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Marconi has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Marco

2. Surname (Last Name)

Marzioni

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

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Are there any relevant conflicts of interest?

Yes

No

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Yes

No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work?

Yes

No

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

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Section 6. Disclosure Statement

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Dr. Marzioni has nothing to disclose.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Anna

2. Surname (Last Name)

Morgando

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Morgando has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Giacomo

2. Surname (Last Name)

Mulinacci

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Dr. Mulinacci has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Luigi	2. Surname (Last Name) Muratori	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Intercept Pharmaceuticals	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Muratori reports personal fees from Intercept Pharmaceuticals, outside the submitted work; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Alessandro

2. Surname (Last Name)

Mussetto

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Are there any relevant conflicts of interest? Yes No

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Dr. Mussetto has nothing to disclose.

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Grazia

2. Surname (Last Name)

Niro

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

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Are there any relevant conflicts of interest? Yes No

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Dr. Niro has nothing to disclose.

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Sarah Elizabeth

2. Surname (Last Name)

O'Donnell

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

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Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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Dr. O'Donnell has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Barbara

2. Surname (Last Name)

Omazzi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Valeria

2. Surname (Last Name)

Pace Palitti

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Dr. Pace Palitti has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Andrea	2. Surname (Last Name) Palermo	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

Section 2. The Work Under Consideration for Publication

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Rinaldo

2. Surname (Last Name)

Pellicano

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

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JHEPR-D-20-00216

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Adriano

2. Surname (Last Name)

Pellicelli

3. Date

19-November-2020

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Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Antonio

2. Surname (Last Name)

Picardi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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19-November-2020

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Corresponding Author's Name

Marco Carbone

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JHEPR-D-20-00216

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Maria Graziella

2. Surname (Last Name)

Pigozzi

3. Date

19-November-2020

4. Are you the corresponding author?

 Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Section 1. Identifying Information

1. Given Name (First Name)

Guido

2. Surname (Last Name)

Poggi

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

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JHEPR-D-20-00216

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Maurizio

2. Surname (Last Name)

Pompili

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19-November-2020

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Corresponding Author's Name

Marco Carbone

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Francesca Romana

2. Surname (Last Name)

Ponziani

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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Dr. Ponziani has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Pietro

2. Surname (Last Name)

Pozzoni

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest?

Yes

No

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No

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Yes

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Vincenzo

2. Surname (Last Name)

Ronca

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Section 4. Intellectual Property -- Patents & Copyrights

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Floriano	2. Surname (Last Name) Rosina	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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Dr. Rosina has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Maurizio

2. Surname (Last Name)

Russello

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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1. Given Name (First Name) Rodolfo	2. Surname (Last Name) Sacco	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Carbone
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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Sacco has nothing to disclose.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Gaetano

2. Surname (Last Name)

Scifo

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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Are there any relevant conflicts of interest?

Yes

No

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Are there any relevant conflicts of interest?

Yes

No

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Yes

No

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Dr. Scifo has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Silvia

2. Surname (Last Name)

Storato

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Natalia

2. Surname (Last Name)

Terreni

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

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Dr. Terreni has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Ester

2. Surname (Last Name)

Vanni

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Rosanna

2. Surname (Last Name)

Venere

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

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JHEPR-D-20-00216

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Yes

No

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Yes

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4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

5. Relationships not covered above.

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Definitions.

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Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

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Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Umberto

2. Surname (Last Name)

Vespasiani Gentilucci

3. Date

19-November-2020

4. Are you the corresponding author?

Yes No

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication**.

Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Intercept Pharmaceuticals	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Shionogi	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

- Yes, the following relationships/conditions/circumstances are present (explain below):
- No other relationships/conditions/circumstances that present a potential conflict of interest

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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Vespasiani Gentilucci reports grants, personal fees and other from Intercept Pharmaceuticals, grants, personal fees and other from Shionogi, outside the submitted work; .

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

1. Identifying information.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes".

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Mauro	2. Surname (Last Name) Viganò	3. Date 19-November-2020
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Marco Viganò
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you know it) JHEPR-D-20-00216		

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Intercept	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Viganò reports personal fees from Intercept, outside the submitted work; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Maria

2. Surname (Last Name)

Vinci

3. Date

19-November-2020

4. Are you the corresponding author?

Yes

No

Corresponding Author's Name

Marco Carbone

5. Manuscript Title

Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis

6. Manuscript Identifying Number (if you know it)

JHEPR-D-20-00216

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest?

Yes

No

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Dr. Vinci has nothing to disclose.

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