

#### 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.

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

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patent

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Section 1.	Identifying Infor	mation				
1. Given Name (Fin Domenico	rst Name)	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 treat		c acid in a large cohort of p	atients with primary biliary cholangitis			
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you 16	know it)				
Section 2.	The Work Under	Consideration for Publ	cation			
any aspect of the s statistical analysis,	ubmitted work (includi etc.)?	ng but not limited to grants, d	n a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,			
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
		1.10

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support <mark>?</mark>	Other?	Comments	
Shionogi		$\checkmark$				
Intercept Pharmaceuticals	$\checkmark$	$\checkmark$				
Aboca		$\checkmark$				
Vesta-Usa	$\checkmark$					



## 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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### Section 6. Disclosure Statement

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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 Inform	ation				
1. Given Name (Fir Leonardo	. Given Name (First Name) 2. Surname (Last Name) eonardo Baiocchi		3. Date 19-November-2020			
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone			
5. Manuscript Title Real-world treatr		icid in a large cohort of par	tients with primary biliary cholangitis			
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kn 16	ow it)				
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Dr. Baiocchi has nothing to disclose.

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1. Given Name (Fir Valentina	I. Given Name (First Name) 2. Surname (Last Name) /alentina Bellia		3. Date 19-Novem	1ber-2020		
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone			
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	ients with primary biliary cholangitis			
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Section 4.	Intellectual Proper	rty Patents & Copyrig	hts			
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work?Yes	✓ No		



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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

Bertino



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1. Given Name (Fir Gaetano	rst Name)	2. Surname (Last Name) Bertino		3. Date 19-November-2020		
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Nan Marco carbone	ne		
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary cl	nolangitis		
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1. Given Name (Fir Roberto	rst Name)	2. Surname (Last Name) Boldizzoni		. Date 9-November-2020		
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone	2		
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Section 2						

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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?		No
Are there any relevant connicts of interest:	v res	

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support <mark>?</mark>	Other?	Comments	
AbbVie		$\checkmark$				
Gilead		$\checkmark$				
Intercept Pharmaceutical		$\checkmark$				
MSD	$\checkmark$					



## 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. 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**



#### Instructions

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#### 4. Intellectual Property.

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patent

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Section 1. Identifying Infor	mation							
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	5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis							
6. Manuscript ldentifying Number (if you JHEPR-D-20-00216	know it)							
Section 2. The Work Under	Consideration for Public	cation						
Did you or your institution <b>at any time</b> 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 V No								
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Section 4. Intellectual Prop	erty Patents & Copyrig	Jhts						
Do you have any patents, whether pla	nned, pending or issued, br	oadly relevant to the work? 🔄 Yes 🛛 🖌 No						



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# Section 6. Disclosure Statement

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Dr. Cannavò has nothing to disclose.

#### **Evaluation and Feedback**



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Section 1. Identifying Inform			
Identifying Inform	ation		
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 a	acid in a large cohort of p	patients with primary biliary	y cholangitis
6. Manuscript Identifying Number (if you kr JHEPR-D-20-00216	now it)		
Section 2. The Work Under Co	onsideration for Publ	ication	
Did you or your institution <b>at any time</b> rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of intere	but not limited to grants, o		
Section 3. Relevant financial	activities outside the	submitted work.	
Place a check in the appropriate boxes i of compensation) with entities as descri clicking the "Add +" box. You should rep Are there any relevant conflicts of intere If yes, please fill out the appropriate info	bed in the instructions. bort relationships that we est?	Jse one line for each entity	r; add as many lines as you need by
Name of Entity	Grant? Personal No Fees?	on-Financial Support? Other? Co	omments
ntercept			
Section 4. Intellectual Proper	rty Patents & Copyr	ights	
Do you have any patents, whether plan			rk? │Yes 🖌 No



## Section 5. Relationships not covered above

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

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Section 1.	Identifying Inform	nation			
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 Co	onsideration for Public	ation		
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Continue (					
Section 4.	Intellectual Proper	rty Patents & Copyrig	hts		
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? 🗌 Yes 🖌 No					



## Section 5. Relationships not covered above

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Dr. Casella has nothing to disclose.

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Section 1.	Identifying Inform	ation				
1. Given Name (First Name) Antonino		2. Surname (Last Name) Castellaneta	3. Date 19-November-2	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 Ider JHEPR-D-20-002	ntifying Number (if you kn 16	now it)				
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Section 3.	Relevant financial	activities outside the s	ubmitted work.			
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Section 4.						
Section 4.	Intellectual Proper	ty Patents & Copyrig	hts			
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? 🗌 Yes 🖌 No						



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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

Cazzagon



Section 1. Identifying Inform	ation					
1. Given Name (First Name) Nora	2. Surname (Last Name) Cazzagon		3. Date 19-November-2020			
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's I Marco Carbone	Name			
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis						
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Name of Entity	Grant•	n-Financial upport? Other? C	omments			
ntercept Pharmaceuticals						
Section 4. Intellectual Proper	rty Patents & Copyrig	Jhts				

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



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

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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.



Section 1. Identifying Inform	nation				
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 ki JHEPR-D-20-00216	now it)				
Section 2. The Work Under C	onsideration for Public	cation			
Did you or your institution <b>at any time</b> 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 V 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 <b>present during the 36 months prior to publication</b> . Are there any relevant conflicts of interest? Yes Yes No					
Section 4. Intellectual Prope	rty Patents & Copyrig	yhts			
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):

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# Section 6. Disclosure Statement

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Dr. Chessa has nothing to disclose.

#### **Evaluation and Feedback**



#### Instructions

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Section 1.	Identifying Inform	ation				
1. Given Name (Fir Ernesto	rst Name)	2. Surname (Last Name) Claar		Date 9-November-2020		
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone			
5. Manuscript Title Real-world treatr	. Manuscript Title eal-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis					
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kr 16	now it)				
Section 2.	The Work Under Co	onsideration for Public	ation			
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of compensation clicking the "Add	he appropriate boxes i ) with entities as descri	n the table to indicate whe bed in the instructions. Us port relationships that wer	ether you have financial relation	onships (regardless of amount as many lines as you need by <b>oths prior to publication</b> .		
Section 4.	Intellectual Proper	rty Patents & Copyrig	hts			
Do you have any	patents, whether plan	ned, pending or issued, bro	oadly relevant to the work? [	Yes 🖌 No		



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Section 1.	Identifying Inform	nation		
1. Given Name (Fir Francesca	rst Name)	2. Surname (Last Name) Colapietro	3. Date 19-November-2020	
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone	
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	ients with primary biliary cholangitis	
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Section 4.	Intellectual Proper	rty Patents & Copyrig	hts	
Do you have any	patents, whether plan	ned, pending or issued, bro	oadly relevant to the work? 🗌 Yes 🖌 No	



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Section 1.	Identifying Inform	ation		
1. Given Name (Fir Raffaele	rst Name)	2. Surname (Last Name) Cozzolongo		3. Date 19-November-2020
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Nam Marco Carbone	ne
5. Manuscript Title Real-world treatr		icid in a large cohort of pa	tients with primary biliary ch	nolangitis
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kn 16	ow it)		
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Section 4.				
Jecuon 4.	Intellectual Proper	ty Patents & Copyrig	hts	
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work?	Yes 🖌 No



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Dr. Cozzolongo has nothing to disclose.

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Section 1.	Identifying Inform	ation		
1. Given Name (Fi Laura	rst Name)	2. Surname (Last Name) Cristoferi		3. Date 19-November-2020
4. Are you the cor	responding author?	Yes No		
5. Manuscript Title Real-world treat		cid in a large cohort of patient	s with primary biliary	cholangitis
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Section 4.				
Section 4.	Intellectual Proper	ty Patents & Copyrights		
Do you have any	patents, whether planı	ned, pending or issued, broadl	y 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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Section 1.	Identifying Inform	nation				
1. Given Name (Fir Maria	rst Name)	2. Surname (Last Name) D'Antò	3. Date 19-November-2020			
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone			
5. Manuscript Title Real-world treatr	5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis					
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kr 16	now it)				
Section 2.	The Work Under Co	onsideration for Public	ation			
any aspect of the s statistical analysis,	ubmitted work (including	but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for a monitoring board, study design, manuscript preparation,			
Section 3.	Relevant financial	activities outside the s	ubmitted work			
of compensation clicking the "Add	he appropriate boxes i ) with entities as descri	n the table to indicate whe ibed in the instructions. Us port relationships that wer	ether you have financial relationships (regardless of amount e one line for each entity; add as many lines as you need by e <b>present during the 36 months prior to publication</b> .			
Section 4.	Intellectual Proper	rty Patents & Copyrig	hts			
Do you have any	patents, whether plan	ned, pending or issued, bro	oadly 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):

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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. D'Antò has nothing to disclose.

### **Evaluation and Feedback**



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

## 5. Relationships not covered above.

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patent

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Section 1.	Identifying Inform	ation		
1. Given Name (Fir Elisabetta	rst Name)	2. Surname (Last Name) Degasperi		3. Date 19-November-2020
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Nam Marco Carbone	ne
5. Manuscript Title Real-world treatr		icid in a large cohort of pa	tients with primary biliary ch	nolangitis
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kn 16	ow it)		
			-	
Section 2.	The Work Under Co	onsideration for Public	ation	
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Section 3.	Relevant financial	activities outside the s	ubmitted work.	
of compensation clicking the "Add	) with entities as descri	bed in the instructions. Us port relationships that wer	e one line for each entity; ac	itionships (regardless of amount dd as many lines as you need by <b>onths prior to publication</b> .
Section 4.				
Jecuon 4.	Intellectual Proper	ty Patents & Copyrig	hts	
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work?	Yes 🖌 No



## Section 5. Relationships not covered above

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1. Given Name (Fir Antonio	rst Name)	2. Surname (Last Name) De Vincentis		3. Date 19-November-2020
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Nam Marco Carbone	e
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary ch	olangitis
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Section 4.				
Section 4.	Intellectual Proper	ty Patents & Copyrig	hts	
Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work?	Yes 🖌 No



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1. Given Name (Fir Marco	rst Name)	2. Surname (Last Name) Distefano		3. Date 19-November-2020
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Nam Marco Carbone	e
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary ch	olangitis
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Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work?	Yes 🖌 No



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Dr. Distefano has nothing to disclose.

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Section 1.	Identifying Infor	mation			
1. Given Name (Fin Stefano		2. Surname (Last Name) Fagiuoli	3. Date 19-November-2020		
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Name Marco Carbone		
5. Manuscript Title Real-world treat		acid in a large cohort of p	atients with primary biliary cholangitis		
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# Are there any relevant conflicts of interest? Yes Ves

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Are there any relevant conflicts of interest?	🖌 Yes	No
Are there any relevant connets of interest:	VICS	

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
Gilead		$\checkmark$				
ABBvie		$\checkmark$				
MSD		$\checkmark$				
Intercept		$\checkmark$				
Novartis		$\checkmark$				
Astellas		$\checkmark$				
Bayer		$\checkmark$				
Kedrion		$\checkmark$				



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.	Deletionshing not sourced should				
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Dr. Fagiuoli 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;

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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						
			-			
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Do you have any	patents, whether plan	ned, pending or issued, bro	oadly relevant to the work? 🗌 Yes 🖌 No			



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Dr. Feletti has nothing to disclose.

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patent

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Section 1.	Identifying Inform	ation				
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 Co	onsideration for Public	ation			
Did you or your institution <b>at any time</b> 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 V No						
Section 3.	Relevant financial	activities outside the s	ubmitted 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 <b>present during the 36 months prior to publication</b> . Are there any relevant conflicts of interest? Yes $\checkmark$ No						
Section 4.	Intellectual Proper	ty Patents & Copyrig	hts			
Do you have any			oadly relevant to the work?			



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# Section 6. Disclosure Statement

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Dr. Floreani has nothing to disclose.

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1. Given Name (Fir Rossana	rst Name)	2. Surname (Last Name) Fontana	3. Date 19-November-2020	0		
4. Are you the corr	responding 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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Do you have any	patents, whether plan	ned, pending or issued, bro	oadly relevant to the work? 🗌 Yes 🖌 No			



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Dr. Fontana has nothing to disclose.

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1. Given Name (Fir Evelise	rst Name)	2. Surname (Last Name) Frazzetto		3. Date 19-November-2020		
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Nar Marco Carbone	ne		
5. Manuscript Title Real-world treatment with obeticholic acid in a large cohort of patients with primary biliary cholangitis						
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Section 4.	Intellectual Proper	rty Patents & Copyrig	ghts			
Do you have any	patents, whether plan	ned, pending or issued, bi	roadly relevant to the work?	Yes 🖌 No		



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Dr. Frazzetto has nothing to disclose.

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1. Given Name (Fir Giovanni	rst Name)	2. Surname (Last Name) Galati	3. Dat 19-Nc	e ovember-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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Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work?	′es 🖌 No		



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Dr. Galati has nothing to disclose.

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Dr. Gerussi has nothing to disclose.

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Dr. Grassi has nothing to disclose.

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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.

Use this section to report 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.

patent

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Invernizzi



Section 1. Identifying Inform	ation					
1. Given Name (First Name) Pietro	2. Surname (Last Name) Invernizzi		3. Date 19-November-2020			
4. Are you the corresponding author?	Yes Ves 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 kr JHEPR-D-20-00216	now it)					
		and the second se				
Section 2. The Work Under Co	onsideration for Public	cation				
Did you or your institution <b>at any time</b> 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 V No						
Section 3. Relevant financial	activities outside the s	ubmitted 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 <b>present during the 36 months prior to publication</b> .						
Are there any relevant conflicts of interest?  Yes No If yes, please fill out the appropriate information below.						
Name of Entity	Grant•	n-Financial upport? Other? Co	omments			
ntercept Pharmaceuticals	$\checkmark$					
Section 4. Intellectual Proper	ty Patents & Copyrig	ghts				

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



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

### **Evaluation and Feedback**



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Section 1. Identifying Inform	ation					
1. Given Name (First Name) Antonio	2. Surname (Last Name) Izzi	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 kr JHEPR-D-20-00216	now it)					
Section 2. The Work Under Co	onsideration for Public	ation				
	but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,				
Section 3. Relevant financial	activities outside the s	ubmitted work.				
of compensation) with entities as descri	bed in the instructions. Us port relationships that wer	ether you have financial relationships (regardless of amount e one line for each entity; add as many lines as you need by e <b>present during the 36 months prior to publication</b> .				
Continue						
Section 4. Intellectual Proper	ty Patents & Copyrig	hts				
Do you have any patents, whether plan	ned, pending or issued, br	oadly relevant to the work? 🗌 Yes 🛛 🗸 No				



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Dr. Izzi has nothing to disclose.

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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				
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Name of Entity	Grant•	n-Financial Support? Other? Comments				
ntercept		speaker for Intercept				
Section 4. Intellectual Proper	rty Patents & Copyri	ghts				

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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Section 1.	Identifying Infor	mation		
1. Given Name (Fii Ana		2. Surname (Last Name) Lleo		3. Date 19-November-2020
<ul><li>4. Are you the corresponding author?</li></ul>		Yes 🖌 No Corresponding Author's Name Marco Carbone		ne
5. Manuscript Title Real-world treat		acid in a large cohort of p	atients with primary biliary c	holangitis
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any aspect of the s statistical analysis,	ubmitted work (includir etc.)?	ng but not limited to grants, c	n a third party (government, cor lata monitoring board, study de	mmercial, private foundation, etc.) for sign, manuscript preparation,
Did you or your ins any aspect of the s statistical analysis,	titution <b>at any time</b> rec ubmitted work (includir	eive payment or services from	n a third party (government, coi	

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Are there any relevant conflicts of interest?		No
Are there any relevant connicts of interest:	v res	

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
Intercept		$\checkmark$				
AlfaSigma		$\checkmark$				
Takeda		$\checkmark$				
Abbvie		$\checkmark$				
Gilead		$\checkmark$				
Merk Sharp & Dohme		$\checkmark$				



# 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

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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; .

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1. Given Name (Fir Francesco	rst Name)	2. Surname (Last Name) Losito		Date -November-2020		
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone			
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Dr. Losito has nothing to disclose.

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Malinverno



Section 1.	Identifying Inform	nation					
1. Given Name (First Name) Federica		2. Surname (Last Name) Malinverno		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 Co	onsideration for Public	ation				
Did you or your institution <b>at any time</b> 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 Ves No							
Section 3.	Relevant financial	activities outside the s	ubmitted work.				
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Section 4.	Intellectual Proper	rty Patents & Copyrig	hts				
Do you have any	patents, whether plan	ned, pending or issued, bro	oadly relevant to the work?	Yes 🖌 No			



# Section 5. Relationships not covered above

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Dr. Malinverno has nothing to disclose.

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1. Given Name (First Name) Clara		2. Surname (Last Name) Mancuso	3. Date 19-Nove	ember-2020			
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5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary cholangitis		
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Marzioni



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4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone		
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Section 1. Identifying Inform	ation				
1. Given Name (First Name) Luigi	2. Surname (Last Name) Muratori		3. Date 19-November-2020		
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Marco Carbone	s Name		
5. Manuscript Title Real-world treatment with obeticholic a	icid in a large cohort of pa	tients with primary bilia	ary cholangitis		
6. Manuscript Identifying Number (if you kn JHEPR-D-20-00216	ow it)				
Section 2. The Work Under Co	onsideration for Public	ation			
Did you or your institution <b>at any time</b> 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 Ves No					
Section 3. Relevant financial	activities outside the s	ubmitted work.			
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Name of Entity	Grant•	n-Financial upport? Other?	Comments		
ntercept Pharmaceuticals					
Section 4. Intellectual Proper	ty Patents & Copyrig	.htc			
nitellectual Proper	ty Patents & Copyrig				

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



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

#### **Evaluation and Feedback**



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Section 1.	Identifying Inform	ation			
1. Given Name (Fir Alessandro	rst Name)	2. Surname (Last Name) Mussetto	3. Date 19-November-2020		
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone		
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary cholangitis		
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kr 16	now it)			
			-		
Section 2.	The Work Under Co	onsideration for Public	ation		
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Section 3.	Relevant financial	activities outside the s	ubmitted work.		
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Section 4.	Intellectual Proper	rty Patents & Copyrig	hts		
Do you have any	patents, whether plan	ned, pending or issued, bro	oadly relevant to the work? 🗌 Yes 🖌 No		



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Dr. Mussetto has nothing to disclose.

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Section 1.	Identifying Inform	ation			
1. Given Name (Fir Grazia	rst Name)	2. Surname (Last Name) Niro		3. Date 19-November-2020	
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Nam Marco Carbone	e	
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary ch	olangitis	
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kr 16	now it)			
			-		
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Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work?	Yes 🖌 No	



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Dr. Niro has nothing to disclose.

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Section 1.	Identifying Inform	ation			
1. Given Name (Fir Sarah Elizabeth	rst Name)	2. Surname (Last Name) O'Donnell	3. Date 19-November-2020		
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone		
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary cholangitis		
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Do you have any	patents, whether plan	ned, pending or issued, br	oadly relevant to the work? 🔄 Yes 🛛 🖌 No		



## Section 5. Relationships not covered above

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Dr. O'Donnell has nothing to disclose.

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1. Given Name (Fir Barbara	rst Name)	2. Surname (Last Name) Omazzi	3. Date 19-Novem	ber-2020	
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone		
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Do you have any	patents, whether plan	ned, pending or issued, bro	oadly relevant to the work?	✓ No	



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1. Given Name (Fir Valeria	rst Name)	2. Surname (Last Name) Pace Palitti	3. Date 19-November-2020		
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone		
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary cholangitis		
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kr 16	now it)			
			-		
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Do you have any			oadly relevant to the work? Yes 🖌 No		



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Dr. Pace Palitti has nothing to disclose.

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Pellicano



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1. Given Name (Fir Maria Graziella	rst Name)	2. Surname (Last Name) Pigozzi	3. Date 19-November-2020			
4. Are you the cor	responding author?	Yes 🗸 No	Corresponding Author's Name Marco Carbone			
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Ponziani



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1. Given Name (Fir Francesca Romai		2. Surname (Last Name) Ponziani	3. Date 19-November-2020			
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Section 4.	Intellectual Proper	rty Patents & Copyrig	hts			
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes 🖌 No						



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Dr. Ronca has nothing to disclose.

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patent

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Section 1.	Identifying Inform	nation					
1. Given Name (Fir Floriano	rst Name)	2. Surname (Last Name) Rosina	3. Date 19-November-2020				
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone				
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary cholangitis				
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			-				
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	-	rty Patents & Copyrig					
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Dr. Rosina has nothing to disclose.

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1. Given Name (Fir Maurizio	rst Name)	2. Surname (Last Name) Russello	3. Date 19-November-2020			
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Section 1.	Identifying Inform	ation				
1. Given Name (Fir Rodolfo	rst Name)	2. Surname (Last Name) Sacco	3. Date 19-November-2020			
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Marco Carbone			
5. Manuscript Title Real-world treatr		acid in a large cohort of par	tients with primary biliary cholangitis			
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Dr. Sacco has nothing to disclose.

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Section 1.	Identifying Inform	nation		
1. Given Name (First Name) Gaetano		2. Surname (Last Name) Scifo		Date 9-November-2020
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Name Marco Carbone	
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	tients with primary biliary cho	langitis
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1. Given Name (First Name) Silvia		2. Surname (Last Name) Storato		Date 9-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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#### 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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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

Terreni



Section 1.	Identifying Inform	nation		
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 treatr		acid in a large cohort of pa	tients with primary biliary cholangitis	
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kr 16	now it)		
Section 2.	The Work Under Co	onsideration for Public	ation	
Did you or your institution <b>at any time</b> 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 V 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 <b>present during the 36 months prior to publication</b> . Are there any relevant conflicts of interest? Yes $\checkmark$ No				
Section 4.	Intellectual Proper	rty Patents & Copyrig	hts	
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes 🖌 No				



# Section 5. Relationships not covered above

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Yes, the following relationships/conditions/circumstances are present (explain below):

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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. Terreni has nothing to disclose.

#### **Evaluation and Feedback**



#### Instructions

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Section 1. Identifying Infor	mation			
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 pa	tients with primary biliary cholangitis		
6. Manuscript Identifying Number (if you JHEPR-D-20-00216	know it)			
Section 2. The Work Under	Consideration for Public	cation		
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Section 4. Intellectual Prope	erty Patents & Copyrig	Jhts		
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? 🗌 Yes 🖌 No				



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Dr. Vanni has nothing to disclose.

#### **Evaluation and Feedback**



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Section 1.	Identifying Inform	nation		
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 Nar Marco Carbone	ne
5. Manuscript Title Real-world treatr		acid in a large cohort of pa	atients with primary biliary c	holangitis
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kr 16	now it)		
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Section 4.				
	Intellectual Proper	rty Patents & Copyri	ghts	
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? 🗌 Yes 🖌 No				



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Dr. Venere has nothing to disclose.

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patent

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Vespasiani Gentilucci



Section 1. Identifying Inform	ation			
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 a	cid in a large cohort of patients with	n primary biliary cholangitis		
6. Manuscript Identifying Number (if you kno JHEPR-D-20-00216	ow it)			
Section 2. The World Under Co				
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Name of Entity	Grant? Personal Non-Financia Fees? Support?	Other? Comments		
Intercept Pharmaceuticals				

Section 4.

Shionogi

#### Intellectual Property -- Patents & Copyrights

 $\checkmark$ 

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

 $\checkmark$ 

 $\checkmark$ 

🖌 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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# 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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Section 1. Identifying Inform	ation			
1. Given Name (First Name) Mauro	2. Surname (Last Name) Viganò		3. Date 19-November-2020	
4. Are you the corresponding author?	Yes ✔ No Corresponding Author's Name Marco Viganò		lame	
5. Manuscript Title Real-world treatment with obeticholic a	cid in a large cohort of pa	tients with primary biliary	/ cholangitis	
6. Manuscript Identifying Number (if you kno JHEPR-D-20-00216	ow it)			
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If yes, please fill out the appropriate information below.				
Name of Entity	Grant•	1-Financial upport? Other? Co	omments	
ntercept				
Section 4. Intellectual Property	ty Patents & Copyrig	ghts		

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



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

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Section 1.	Identifying Inform	nation		
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 treatr		acid in a large cohort of pa	tients with primary biliary cholangitis	
6. Manuscript Ider JHEPR-D-20-002	ntifying Number (if you kr 16	now it)		
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Did you or your institution <b>at any time</b> 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 V 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 <b>present during the 36 months prior to publication</b> . Are there any relevant conflicts of interest? Yes $\checkmark$ No				
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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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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. Vinci has nothing to disclose.

#### **Evaluation and Feedback**