

#### **Instructions**

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

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

Assouline



Section 1. Identifying Inform	ation	
1. Given Name (First Name) Sarit	2. Surname (Last Name) Assouline	3. Date 27-August-2014
4. Are you the corresponding author?	Yes V No	Corresponding Author's Name Katherine Borden
5. Manuscript Title A Phase I trial of ribavirin and low-dose elevated eIF4E	cytarabine for the treatm	ent of relapsed and refractory acute myeloid leukemia with
6. Manuscript Identifying Number (if you kn HAEMATOL/2014/111245	ow it)	
Section 2. The Work Under Co	onsideration for Publi	cation
	but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
If yes, please fill out the appropriate info Excess rows can be removed by pressing		ve more than one entity press the "ADD" button to add a row.
Name of Institution/Company	Grant	on-Financial Other? Comments
Pharmascience		Provision of ribavirin for use in the clinical trial
Section 3. Relevant financial	activities outside the	submitted work.
of compensation) with entities as descri	bed in the instructions. U	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re present during the 36 months prior to publication.
Are there any relevant conflicts of intere	est? Yes V No	
Section 4. Intellectual Proper	ty Patents & Copyri	ghts
Do you have any patents, whether plant	ned, pending or issued, b	roadly relevant to the work? Yes V No

Assouline



Section 5.	
Section 5.	Relationships not covered above
	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
Yes, the follow	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	tionships/conditions/circumstances that present a potential conflict of interest
	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. rnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Assouline rep	ports non-financial support from Pharmascience, during the conduct of the study.

### **Evaluation and Feedback**

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Section 1. Identifying I	nformation		
Given Name (First Name) Biljana	Surname (Last Name)     Culjkovic-Kraljacic	3. Date 26-August-2014	
4. Are you the corresponding autho		Corresponding Author's Name Katherine LB Borden & Sarit Assouline	
elevated elF4E	•	t of relapsed and refractory acute myeloid leukemia w	rith
6. Manuscript Identifying Number (i HAEMATOL/2014/111245	you know it)		
Section 2. The Work Un	der Consideration for Publicat	tion	
	cluding but not limited to grants, data	third party (government, commercial, private foundation, et monitoring board, study design, manuscript preparation,	tc.) for
Section 3. Relevant fina	ncial activities outside the sul	hmitted work	
Place a check in the appropriate of compensation) with entities as	poxes in the table to indicate wheth described in the instructions. Use ould report relationships that were	her you have financial relationships (regardless of amo one line for each entity; add as many lines as you need present during the 36 months prior to publication.	d by
Section 4. Intellectual P	roperty Patents & Copyrigh	ts	
		ndly relevant to the work?  Yes  No More than one entity press the "ADD" button to add a	ı row.
Patent?	Pending? Issued? Licensed? Ro	oyalties? Comments	



pre-cancerous lesions. pending to UdeM & PharmaScience.

## **ICMJE Form for Disclosure of Potential Conflicts of Interest**

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments	
Combination Therapy using Ribavirin as elF4E inhibitor and a therapeutically effective amount of a hedgehog pathway inhibitor, such as GDC-0449 aims at overcoming resistance developed in patients during anti-neoplastic treatment. The invention also relates to the use of a combination therapy for treating patients with cancer or precancerous lesions.	V				UdeM & PharmaScience		
Section 5.  Relationships not covered above							
potentially influencing, what yo	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 accep On occasion, journals may ask a							ents.
Section 6. Disclosure S	tatement						
Based on the above disclosures, below.	this form wi	ll automa	tically gene	erate a disclo	osure statement, v	which will appear in the box	

Dr. Culjkovic-Kraljacic has a patent Combination Therapy using Ribavirin as eIF4E inhibitor and a therapeutically effective amount of a hedgehog pathway inhibitor, such as GDC-0449 aims at overcoming resistance developed in patients during anti-neoplastic treatment. The invention also relates to the use of a combination therapy for treating patients with cancer or



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Bergeron



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1. Given Name (First Name) Julie	2. Surname (Last Name) Bergeron	3. Date 26-August-2014
4. Are you the corresponding author?	Yes V No	Corresponding Author's Name Katherine Borden
5. Manuscript Title A Phase I trial of ribavirin and low-dose elevated eIF4E	e cytarabine for the treatm	ent of relapsed and refractory acute myeloid leukemia with
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Bergeron



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Dr. Bergeron ha	s nothing to disclose.

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Caplan



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4. Are you the corresponding author?	Yes V No	Corresponding Author's Name Katherine Borden and Sarit Assouline
5. Manuscript Title A Phase I trial of ribavirin and low-dose elevated eIF4E	e cytarabine for the treatme	ent of relapsed and refractory acute myeloid leukemia with
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any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of inter	g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
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Caplan



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Dr. Caplan has n	othing to disclose.

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Cocolakis



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5. Manuscript Title A Phase I trial of ribavirin and low-dose elevated elF4E	e cytarabine for the treatm	ent of relapsed and refractory acute myeloid leukemia with
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Do you have any patents, whether plan		

Cocolakis



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

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

Lau 1



Section 1. Identifying Inforn	nation	
		2.0.
1. Given Name (First Name) Cara	2. Surname (Last Name) Lau	3. Date 26-August-2014
4. Are you the corresponding author?	Yes V No	Corresponding Author's Name Kathy Borden
5. Manuscript Title Phase I trial of ribavirin and low-dose o	cytarabine	·
6. Manuscript Identifying Number (if you ki HAEMATOL/2014/111245	now it)	_
Section 2. The West Haday C		
The Work Under C	onsideration for Public	cation
	g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
Section 3. Relevant financial	activities outside the	submitted work.
of compensation) with entities as descr	ibed in the instructions. Us port relationships that we	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re <b>present during the 36 months prior to publication</b> .
·		
Section 4. Intellectual Prope	rty Patents & Copyri	ghts
Do you have any patents, whether plan	ned, pending or issued, br	roadly relevant to the work? Yes V No

Lau



Section 5.	Relationships not covered above
	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
Yes, the follo	owing relationships/conditions/circumstances are present (explain below):
✓ No other rela	ationships/conditions/circumstances that present a potential conflict of interest
	nanuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. Irnals may ask authors to disclose further information about reported relationships.
Section 6.	
Section 6.	Disclosure Statement
Based on the ab below.	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box

### **Evaluation and Feedback**

 $Please\ visit\ \underline{http://www.icmje.org/cgi-bin/feedback}\ to\ provide\ feedback\ on\ your\ experience\ with\ completing\ this\ form.$ 

Lau 3



#### **Instructions**

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

Lambert 1



Section 1. Identifying Informa	ation	
1. Given Name (First Name) Caroline	2. Surname (Last Name) Lambert	3. Date 26-August-2014
4. Are you the corresponding author?	Yes V No	Corresponding Author's Name Katherine Borden
5. Manuscript Title A Phase I trial of ribavirin and low-dose of refractory acute myeloid leukemia with a	•	ent of relapsed and
6. Manuscript Identifying Number (if you kno HAEMATOL/2014/111245	ow it)	
Section 2. The Work Under Co	nsideration for Public	cation
, , , , , , , , , , , , , , , , , , ,	. ,	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,
Are there any relevant conflicts of interes	st? Yes No	
Section 3. Relevant financial a	activities outside the s	ubmitted work.
of compensation) with entities as describ	bed in the instructions. Us	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by se <b>present during the 36 months prior to publication</b> .
Are there any relevant conflicts of interes	st? Yes V No	
Section 4. Intellectual Propert	ty Patents & Copyric	yhts
Do you have any patents, whether plann	ned, pending or issued, br	oadly relevant to the work? Yes V No

Lambert



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.
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### Relevant financial activities outside the submitted work.

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earning royalties or not

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



Section 1.	Identifying Inform	ation		
1. Given Name (Fi Hiba	rst Name)	2. Surname (Last Name) Zahreddine		3. Date 26-August-2014
4. Are you the cor	responding author?	Yes No	Corresponding Author	
5. Manuscript Title A Phase I trial of elevated eIF4E		rytarabine for the treatme	nt of relapsed and ref	ractory acute myeloid leukemia with
6. Manuscript Ider HAEMATOL/2014	ntifying Number (if you kno 4/111245	ow it)		
Section 2.	The Work Under Co	nsideration for Public	ation	
any aspect of the s statistical analysis, Are there any rel If yes, please fill o	ntitution <b>at any time</b> receive ubmitted work (including etc.)?  evant conflicts of intere	ve payment or services from but not limited to grants, danst?  Yes No Normation below. If you have	a third party (governmer ta monitoring board, stu	nt, commercial, private foundation, etc.) for dy design, manuscript preparation, y press the "ADD" button to add a row.
Name of Institut	ion/Company	Grant	-Financial other?	Comments
Cole Fellowship  CNRS Lebanon				
Section 3.	Relevant financial a	activities outside the s	ubmitted work.	
of compensation clicking the "Add	) with entities as describ	oed in the instructions. Us ort relationships that wer	e one line for each ent	al relationships (regardless of amount tity; add as many lines as you need by <b>36 months prior to publication</b> .
Section 4.	Intellectual Propert	ty Patents & Copyrig	hts	
If yes, please fill o			•	vork? 🗸 Yes 🔲 No y press the "ADD" button to add a row.



Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
Combination Therapy using Ribavirin as eIF4E inhibitor and a therapeutically effective amount of a hedgehog pathway inhibitor, such as GDC-0449 aims at overcoming resistance developed in patients during anti-neoplastic treatment. The invention also relates to the use of a combination therapy for treating patients with cancer or precancerous lesions.	V				UdeM & PharmaScience	

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):				
<b>✓</b> No other rela	tionships/conditions/circumstances that present a potential conflict of interest			

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## Section 6. Disclosure Statement

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Dr. Zahreddine reports personal fees from Cole Fellowship, personal fees from CNRS Lebanon, during the conduct of the study; In addition, Dr. Zahreddine has a patent Combination Therapy using Ribavirin as eIF4E inhibitor and a therapeutically effective amount of a hedgehog pathway inhibitor, such as GDC-0449 aims at overcoming resistance developed in patients during anti-neoplastic treatment. The invention also relates to the use of a combination therapy for treating patients with cancer or pre-cancerous lesions. pending to UdeM & PharmaScience.



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earning royalties or not

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

patent

Miller



Section 1. Identifying Inform	nation				
identifying inform	nation				
1. Given Name (First Name) Wilson	2. Surname (Last Name) Miller	3. Date 28-August-2014			
4. Are you the corresponding author?	Yes V No	Corresponding Author's Name Katherine LB Borden and Sarit Assouline			
5. Manuscript Title A Phase I trial of ribavirin and low-dose elevated eIF4E	e cytarabine for the treatmo	ent of relapsed and refractory acute myeloid leukemia with			
6. Manuscript Identifying Number (if you k HAEMATOL/2014/111245	now it)				
Section 2. The Work Under C	onsideration for Publi	cation			
any aspect of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of inter	g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,			
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 No					
Section 4. Intellectual Prope	rty Patents & Copyri	ghts			
Do you have any patents, whether plar	nned, pending or issued, bi	roadly relevant to the work? Yes V No			

Miller



Section 5.	
Section 5.	Relationships not covered above
	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
Yes, the follow	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	tionships/conditions/circumstances that present a potential conflict of interest
	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. rnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Miller has no	thing to disclose.

### **Evaluation and Feedback**

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Miller 3



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

Borden 1



Section 1. Identifying Inform	nation			
Given Name (First Name)  Katherine	2. Surname (Last Name) Borden	3. Date 26-August-2014		
4. Are you the corresponding author?	<b>✓</b> Yes			
5. Manuscript Title A Phase I trial of ribavirin and low-dose elevated eIF4E	cytarabine for the treatment of rela	psed and refractory acute myeloid leukemia with		
6. Manuscript Identifying Number (if you kn HAEMATOL/2014/111245	now it)			
Section 2. The Work Under Co	onsideration for Publication			
any aspect of the submitted work (including statistical analysis, etc.)?	but not limited to grants, data monitor	ty (government, commercial, private foundation, etc.) for ing board, study design, manuscript preparation,		
Are there any relevant conflicts of intere		an one entity press the "ADD" button to add a row.		
Excess rows can be removed by pressing		button to add a row.		
Name of Institution/Company	Grant? Personal Non-Financia Support?	Other? Comments		
Leukemia and Lymphoma Society				
NIH				
Pharmascience Inc, Montreal, Canada		Provided ribavirin free of charge for the trial		
Section 3. Relevant financial	activities outside the submitte	d work.		
of compensation) with entities as descri clicking the "Add +" box. You should rep	ibed in the instructions. Use one line port relationships that were <b>presen</b>	have financial relationships (regardless of amount of for each entity; add as many lines as you need by the top the to		
Are there any relevant conflicts of intere	est? Yes V No			
Section 4. Intellectual Proper	rty Patents & Copyrights			
		West of the small 2 Tel Vest T		
Do you have any patents, whether plan	ned, pending or issued, broadly rele	evant to the work? 🔽 Yes 🔝 No		

Borden 2



If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments	
Submitted patent on Gli1 inducible drug glucrondiation	~				University of Montreal and Pharmascience Inc	This is preferal to this paper but the idea of looking for elevated Gli1 as a marker of drug resistance is related	
Section 5. Balasianaki							
Are there other relationships or	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):  Volume value of interest in the following relationships/conditions/circumstances that present a potential conflict of interest							
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Dr. Borden reports grants from Pharmascience Inc, Montreal, C patent on Gli1 inducible drug g	anada, durir	ng the co	nduct of the	study; In a	ddition, Dr. Borde	n has a patent Submitted	

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Borden 3