

Instructions

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Section 1.	Identifying Infor	mation	
1. Given Name (Fir Jeffrey	rst Name)	2. Surname (Last Name) Clark	3. Date 06-January-2021
4. Are you the corr	responding author?	✓ Yes No	

5. Manuscript Title

A phase 1b clinical trial of LDE225 (Sonidegib) in combination with fluorouracil, leucovorin, oxaliplatin, and irinotecan (FOLFIRINOX) in previously untreated locally advanced or metastatic pancreatic cancer

6. Manuscript Identifying Number (if you know it)

APC-20-41

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row	1.
Excess rows can be removed by pressing the "X" button.	

Name of Institution/Company	Grant?	Personal Fees	Non-Financial Support <mark>?</mark>	Other?	Comments	
NIH/NCI	\checkmark					

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



Section 5. Relationships not covered above

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This work was partially funded by P30CA06516 (Benz) (NCI-ASCO Clinical Investigator Team Leadership Supplemental Award NIH/NCI/DFCI/Subaward to MGH)

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Section 1. Identifying Infor	mation	
1. Given Name (First Name) Nora	2. Surname (Last Name) Horick	3. Date 07-January-2021
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Jeffrey Clark
5. Manuscript Title A Phase 1b clinical trial of LDE225 (So (FOLFIRINOX) in previously untreated	5	rith fluorouracil, leucovorin, oxaliplatin, and irinotecan static pancreatic adenocarcinoma
6. Manuscript Identifying Number (if you	know it)	

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🖌 No

Are there any relevant conflicts of interest?		Yes	
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Are there any relevant conflicts of interest?	Yes	\checkmark	No
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	1 1		



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Dr. Horick has nothing to disclose.

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Section 1.	Identifying Infor	mation		
1. Given Name (Fii Jill	rst Name)	2. Surname (Last Name) Allen		3. Date 12-January-2021
4. Are you the corr	responding author?	Yes 🖌 No	Corresponding Author's N Jeffrey Clark	ame
	clinical trial of LDE22	5	ion with fluorouracil, leucov tatic pancreatic adenocarci	vorin, oxaliplatin, and irinotecan noma

6. Manuscript Identifying Number (if you know it)

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🖌 No

Are there any relevant conflicts of interest?		Yes	
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Dr. Allen has nothing to disclose.

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1. Given Name (Fi Lawrence	rst Name)	2. Surname (Last Name) Blaszkowsky	3. Date 08-January-2021
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Jeffrey William Clark
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			•	

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4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Jeffrey Clark	e
	cal trial of LDE225 (Sor	5	th fluorouracil, leucovorin, oxi atic pancreatic adenocarcinol	•

6. Manuscript Identifying Number (if you know it)

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.)?

🖌 No

Are there any relevant conflicts of interest?		Yes
---	--	-----

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**.

No

Are there any relevant conflicts of interest? Yes

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees	Non-Financial Support?	Other?	Comments	
Agios				\checkmark	Consultant	
Amylin				\checkmark	Consultant, Expert Testimony	
Astra-Zeneca				\checkmark	Consultant	
Bain Capital				\checkmark	Consultant	
CytomX				\checkmark	Director, unexercised stock options	
Daiichi-Sankyo				\checkmark	Consultant	
Eli Lilly				\checkmark	Consultant, Expert Testimony	



Name of Entity	Grant?	Personal Fees ?	Non-Financial Support?	Other?	Comments	
Entrinsic Health					Consultant, unexercised stock options	
Evolveimmune Therapeutics				\checkmark	Co-Founder	
Genentech				\checkmark	Consultant	
Merck				\checkmark	Consultant	
Taiho				\checkmark	Consultant	
Unum				\checkmark	Consultant	

-					
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2			U		

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

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Charles S. Fuchs reports consulting role for Agios, Amylin Pharmaceuticals, Astra-Zeneca, Bain Capital, CytomX Therapeutics, Daiichi-Sankyo, Eli Lilly, Entrinsic Health, Evolveimmune Therapeutics, Genentech, Merck, Taiho, and Unum Therapeutics. He also serves as a Director for CytomX Therapeutics and owns unexercised stock options for CytomX and Entrinsic Health. He is a co-Founder of Evolveimmune Therapeutics and has equity in this private company. He has provided expert testimony for Amylin Pharmaceuticals and Eli Lilly.

Evaluation and Feedback



Instructions

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4. Intellectual Property.

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

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Section 1.	Identifying Infor	mation		
1. Given Name (F Brian	irst Name)	2. Surname (Last Name) Wolpin	3. Date 14-January-2021	
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Name Jeffrey Clark	
	cal trial of LDE225 (So	5	ith fluorouracil, leucovorin, oxaliplatin, and irinotecan tatic pancreatic adenocarcinoma)

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🖌 No

Are there any relevant conflicts of interest?	Y	/es
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No

Are there any relevant conflicts of interest? Yes

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
Eli Lilly and Company	\checkmark			\checkmark	Other: research funding	
Grail				\checkmark	Other: Consultant	
Celgene, Inc				\checkmark	Other: research funding/consultant	
BioLineRx				\checkmark	Other: Consultant	



Section 4. Intellectual Property -- Patents & Copyrights

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

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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Dr. Wolpin reports grants and other from Eli Lilly and Company, other from Grail, other from Celgene, Inc, other from BioLineRx, outside the submitted work; .

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Section 1.	Identifying Infor	mation	
1. Given Name (Fir Robert	st Name)	2. Surname (Last Name) Mayer	3. Date 07-January-2021
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Name Jeffrey W. Clark, MD
	Clinical Trial of LDE22	-	ation with Fluorouracil, Leucovorin, Oxaliplatin, and ced or Metastatic Pancreatic Adenocarcinoma

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest?		Yes	\checkmark	No
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Are there any relevant conflicts of interest?	Yes	\checkmark	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	
		•	



Section 5. Relationships not covered above

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Dr. Mayer has nothing to disclose.

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Section 1.	Identifying Infor	mation			
1. Given Name (Fi Jason	irst Name)	2. Surnamo Faris	e (Last Name)		3. Date 14-January-2021
4. Are you the cor	rresponding author?	Yes	✓ No	Corresponding Author's Na Jeffrey Clark, MD	me
5. Manuscript Titl		onideaib) in c	ombination w	ith fluorouracil, leucovorin,	oxaliplatin and irinotecan

(FOLFIRINOX) in previously untreated locally advanced or metastatic pancreatic adenocarcinoma

6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest?	Ves Yes	5 🗌 No
---	---------	--------

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.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
Novartis				\checkmark	Full-time employee of Novartis from 2015-2019	

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
Curis	\checkmark				
Incyte	\checkmark				
Tizona	\checkmark				



Name of Entity	Grant <mark>?</mark>	Personal Fees ?	Non-Financial Support?	Other?	Comments
Astellas	\checkmark				
H3 Biomedicine	\checkmark				

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. Faris reports other from Novartis, during the conduct of the study; grants from Curis, grants from Incyte, grants from Tizona, grants from Astellas, grants from H3 Biomedicine, outside the submitted work; .



Evaluation and Feedback



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Section 1. Identifying Infor	mation	
1. Given Name (First Name) Jennifer	2. Surname (Last Name) Chan	3. Date 13-January-2021
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Jeffrey W. Clark
5. Manuscript Title A Phase 1b clinical trial of LDE225 (So	nidegib) in combination wit	h fluorouracil, leucovorin, oxaliplatin, and irinotecan

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🖌 No

Are there any relevant conflicts of interest?		Yes	
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If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
Advanced Accelerator Applications		\checkmark				
Lexicon		\checkmark				
lpsen		\checkmark				
Crinetics		\checkmark				
Novartis		\checkmark				
Merck				\checkmark	stock ownership	



Section 4. Intellectual Property -- Patents & Copyrights

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

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Dr. Chan reports personal fees from Advanced Accelerator Applications, personal fees from Lexicon, personal fees from Ipsen, personal fees from Crinetics, personal fees from Novartis, other from Merck, outside the submitted work; .

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Section 1.	Identifying Infor	mation			
1. Given Name (Fi Kimmie	rst Name)	2. Surnan Ng	ne (Last Name)		3. Date 09-January-2021
4. Are you the cor	responding author?	Yes	✓ No	Corresponding Author's Na Jeffrey W. Clark	me
5. Manuscript Title	e				

A Phase 1b clinical trial of LDE225 (Sonidegib) in combination with fluorouracil, leucovorin, oxaliplatin, and irinotecan (FOLFIRINOX) in previously untreated locally advanced or metastatic pancreatic adenocarcinoma

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Are there any relevant conflicts of interest? \checkmark Yes No.	Are there an	y relevant	conflicts	of interest?	\checkmark	Yes		No
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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.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support <mark>?</mark>	Other?	Comments	
National Cancer Institute	\checkmark					
Department of Defense	\checkmark					

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	
Pharmavite, LLC	\checkmark		\checkmark			
Evergrande Group			\checkmark			



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Janssen	\checkmark				
Revolution Medicines	\checkmark				
Genentech	\checkmark				
Gilead Sciences	\checkmark				
Seattle Genetics		\checkmark			
Array Biopharma		\checkmark			
BiomX		\checkmark			
X-Biotix Therapeutics		\checkmark			

Section 4.

Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work?	Yes	\checkmark	No
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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. Ng reports grants from National Cancer Institute, grants from Department of Defense, during the conduct of the study; grants and non-financial support from Pharmavite, LLC, non-financial support from Evergrande Group, grants from Janssen, grants from Revolution Medicines, grants from Genentech, grants from Gilead Sciences, personal fees from Seattle Genetics, personal fees from Array Biopharma, personal fees from BiomX, personal fees from X-Biotix Therapeutics, outside the submitted work; .

Evaluation and Feedback



Instructions

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Section 1.	Identifying Infor	mation			
1. Given Name (Fi Nadine	rst Name)	2. Surname (Last Name) Jackson McCleary	3. Date 11-January-2021		
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Name Jeffrey W. Clark		
	cal trial of LDE225 (So	5	ith fluorouracil, leucovorin, oxaliplatin, and irinotecan tatic pancreatic adenocarcinoma		
6. Manuscript Ide	ntifying Number (if you	know it)	•		

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🖌 No

Are there any relevant conflicts of interest?		Yes
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Are there any relevant conflicts of interest?	Yes	\checkmark	No
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Do you have any patents, whether planne	d, pending or issued, broadly relevant to the work? [Yes	🖌 No



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Dr. Jackson McCleary has nothing to disclose.

Evaluation and Feedback



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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



Section 1. Ide	ntifying Infor	mation		
1. Given Name (First Na Thomas	me)	2. Surname (Last Name) Abrams		3. Date 11-January-2021
4. Are you the correspo	nding author?	Yes 🖌 No	Corresponding Author's Na Jeffrey Clark	me
5. Manuscript Title A Phase 1b clinical tria	al of LDE225 (So	nidegib) in combination wi	th fluorouracil, leucovorin, c	oxaliplatin, and irinotecan

(FOLFIRINOX) in previously untreated locally advanced or metastatic pancreatic adenocarcinoma

6. Manuscript Identifying Number (if you know it)

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🖌 No

Are there any relevant conflicts of interest? Yes

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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	
Merck		\checkmark			Advisory Board	
Agios		\checkmark			Advisory Board	
lpsen		\checkmark			Advisory Board	
Exelixis		\checkmark			Advisory Board	
Bristol Myers Squibb		\checkmark			Advisory Board	
Genentech		\checkmark			Advisory Board	
Biogen Idec				\checkmark	Stock Ownership	



Section 4. Intellectual Property -- Patents & Copyrights

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

Section 5. Relationships not covered above

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Section 6. Disclosure Statement

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Dr. Abrams reports personal fees from Merck, personal fees from Agios, personal fees from Ipsen, personal fees from Exelixis, personal fees from Bristol Myers Squibb, personal fees from Genentech, other from Biogen Idec, outside the submitted work; .

Evaluation and Feedback



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Section 1. Identifying Infor	mation	
1. Given Name (First Name) David	2. Surname (Last Name) Ryan	3. Date 25-February-2012
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Jeffrey W. Clark
5. Manuscript Title A Phase 1b clinical trial of LDE225 (So	nidegib) in combination wi	h fluorouracil, leucovorin, oxaliplatin,and irinotecan

(FOLFIRINOX) in previously untreated locally advanced or metastatic pancreatic adenocarcinoma

6. Manuscript Identifying Number (if you know it)

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.)?

🖌 No

Are there any relevant conflicts of interest?		Yes
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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 <mark>?</mark>	Other?	Comments	
Acworth Pharmaceuticals				\checkmark	equity	
MPM Capital		\checkmark		\checkmark	equity	
Thrive Earlier Detection				\checkmark	equity	
Gritstone Oncology		\checkmark				
Maverick Therapeutics		\checkmark				
Johns Hopkins University Press		\checkmark				
Uptodate		\checkmark				
McGraw Hill		\checkmark				



Name of Entity	Grant?	Personal Fees	Non-Financial Support?	Other?	Comments
SU2C	\checkmark				
Exact Sciences				\checkmark	equity

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

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Dr. Ryan reports other from Acworth Pharmaceuticals, personal fees and other from MPM Capital, other from Thrive Earlier Detection, personal fees from Gritstone Oncology, personal fees from Maverick Therapeutics, personal fees from Johns Hopkins University Press, personal fees from Uptodate, personal fees from McGraw Hill, grants from SU2C, other from Exact Sciences, outside the submitted work;



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Section 1. Identifying Infor	mation			
1. Given Name (First Name) Eunice	2. Surname (Last Name) Kwak	3. Date 13-January-2021		
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Jeffrey Clark		
5. Manuscript Title A Phase 1b clinical trial of LDE225 (So (FOLFIRINOX) in previously untreated	5	h fluorouracil, leucovorin, oxaliplatin, and irinotecan atic pancreatic adenocarcinoma		
6. Manuscript Identifying Number (if you APC-20-41	know it)			

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest?		Yes	\checkmark	No
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No

Are there any relevant conflicts of interest? \checkmark Yes

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees	Non-Financial Support?	Other?	Comments	
Novartis				\checkmark	Eunice Kwak is currently employed by Novartis	

Section 4.	-	- •	
	Sec		n 4
	260		

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. Kwak reports other from Novartis, outside the submitted work; .

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1. Given Name (F Theodore	irst Name)	2. Surname (Last Name) Hong		3. Date 07-January-2021	
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Name Jeffrey Clark		
	ical trial of LDE225 (So	5	vith fluorouracil, leucovorin tatic pancreatic adenocarci	, oxaliplatin, and irinotecan noma	

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🖌 No

Are there any relevant conflicts of interest?		Yes
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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
Merck		\checkmark			Consulting
Synthetic Biologics		\checkmark			Consulting
Novocure		\checkmark			Consulting

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. Hong reports personal fees from Merck, personal fees from Synthetic Biologics, personal fees from Novocure, outside the submitted work; .

Evaluation and Feedback