

Instructions

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

patent



Section 1. Identifying Inform	mation	
1. Given Name (First Name)	2. Surname (Last Name)	3. Date 11/7/16
4. Are you the corresponding author?	Yes No	Corresponding Author's Name Vivek Subbiah
5. Manuscript Title Phase I Dose Escalation Study of Multi- with Colorectal Cancer and Advanced	kinase VEGF Inhibitor Rego Cancer	orafenIb and Anti-EGFR Antibody Cetuximab in Patients
Manuscript Identifying Number (if you k 90380-INS-CMED-RV-2	now it)	
Section 2. The Work Under C	onsideration for Public	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 s	ubmitted work.
of compensation) with entities as descr clicking the "Add +" box. You should re Are there any relevant conflicts of inter	ribed in the instructions. Us port relationships that wer est? Kyes No Poly CEOF For quity 12 + CV	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. Sundation Medicine Stroundation Medicine
Intellectual Prope	rty Patents & Copyrig	ghts
Do you have any patents, whether plan	ned, pending or issued, br	roadly relevant to the work? Yes No



Section 5.	Relationships n	ot covered above	ATTAY MADE	以外群省和新兴发发力的 对	
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_	wing relationships/c				
At the time of m	anuscript acceptance	e, journals will ask au	uthors to confirm an	d, if necessary, update their or reported relationships.	disclosure statements
Section 6.	Disclosure State	ment			
Based on the abo	ove disclosures, this f	form will automatica	lly generate a disclo	osure statement, which will a	ppear in the box
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administrative support, etc.

Amini



Section 1. Identifying Inform	nation	
1. Given Name (First Name) Behrang	2. Surname (Last Name) Amini	3. Date 07-November-2016
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Vivek Subbiah
Manuscript Title Phase I Dose Escalation Study of Multi- with Colorectal Cancer and Advanced		orafenib and Anti-EGFR Antibody Cetuximab in Patients
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of compensation) with entities as descri	ribed in the instructions. Use port relationships that we	nether 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.
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Do you have any patents, whether plan	nned, pending or issued, bi	roadly relevant to the work? Yes Vo

Amini



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	owing relationships/conditions/circumstances are present (explain below): ationships/conditions/circumstances that present a potential conflict of interest
At the time of m	nanuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. Urnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
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Dr. Amini has no	othing to disclose.

Evaluation and Feedback

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Eng



Section 1. Identifying Info	rmation	1881, M. P. S. S.		
Given Name (First Name) Cathy	2. Surname (Last Na Eng	me)	3. Date 07-Novembe	er-2016
4. Are you the corresponding author?	☐ Yes ✓ No	Correspon Vivek Sub	ding Author's Name biah	
Manuscript Title Phase I Dose Escalation Study of Mul with Colorectal Cancer and Advance	ti-kinase VEGF Inhibitoi d Cancer	r Regorafenib and	Anti-EGFR Antibody Cetuxim	ab in Patients
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Section 2. The Work Under	· Consideration for P	Publication		
Did you or your institution at any time re any aspect of the submitted work (includ statistical analysis, etc.)? Are there any relevant conflicts of int	ing but not limited to grai	nts, data monitoring	g board, study design, manuscrip	e roundation, etc.) for it preparation,
Section 3. Relevant financi	al activities outside	the submitted	work.	
Place a check in the appropriate boxe of compensation) with entities as desclicking the "Add +" box. You should Are there any relevant conflicts of int If yes, please fill out the appropriate in	scribed in the instruction report relationships that erest?	ns. Use one line fo	or each entity; add as many lin	es as you need by
Name of Entity	Grant? Personal Fees?	Non-Financial Support?	Other? Comments	
Daiichi	V		Research Grant	
Keryx	V		Research Grant	
Genentech			✓ Speakers Bureau	
Roche/Genentech			✓ Honoraria	
Bayer			✓ Honoraria	



Section 4.	Intellectual Property Patents & Copyrights
	intellectual Property Patents & Copyrights
Do you have any	y patents, whether planned, pending or issued, broadly relevant to the work? Yes V No
Cartina	
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Are there other potentially influ	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	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	ationships/conditions/circumstances that present a potential conflict of interest
At the time of m On occasion, jou	anuscript 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.
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Based on the abo below.	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Eng reports of Bayer, outside t	grants from Daiichi, grants from Keryx, other from Genentech, other from Roche/Genentech, other from he submitted work; .

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Fabrizio



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Given Name (First Name) David	2. Surname (Last Name) Fabrizio	3. Date 10-November-2016
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Vivek Subbiah
5. Manuscript Title Phase I Dose Escalation Study of Multi- with Colorectal Cancer and Advanced (orafenib and Anti-EGFR Antibody Cetuximab in Patients
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statistical analysis, etc.)? Are there any relevant conflicts of interest	est? Yes No	ata monitoring board, study design, manuscript preparation,
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Name of Entity	Grant	n-Financial other? Comments
Foundation Medicine		✓ Employee and stockholder
Section 4. Intellectual Proper	ty Patents & Copyrig	ghts
Do you have any patents, whether plant If yes, please fill out the appropriate info Excess rows can be removed by pressing	ormation below. If you hav	oadly relevant to the work? Yes No re more than one entity press the "ADD" button to add a row.

Fabrizio



Patent?	Pending? Issued?	Licensed ? Royalties ?	Licensee?	Comments
Targeted therapeutics based on engineered proteins that bind EGFR				
Section 5. Relationshi	ps not covered abo	ve		
Are there other relationships or potentially influencing, what yo			influenced, or th	nat give the appearance of
Yes, the following relationsh No other relationships/cond			8	est
At the time of manuscript accep On occasion, journals may ask a				pdate their disclosure statements. Iships.
Section 6. Disclosure S	tatement			
Based on the above disclosures, below.	this form will automat	tically generate a disclo	sure statement,	which will appear in the box
Dr. Fabrizio reports other from l Targeted therapeutics based or			work; In additio	on, Dr. Fabrizio has a patent
Evaluation and Feedbac				
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Fabrizio



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Falchook



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4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Vivek Subbiah
5. Manuscript Title Phase I Dose Escalation Study of Multi- with Colorectal Cancer and Advanced	kinase VEGF Inhibitor Rego Cancer	orafenib and Anti-EGFR Antibody Cetuximab in Patients
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Section 1.	Identifying Inform	nation		
1. Given Name (Fi Siqing	rst Name)	2. Surname Fu	(Last Name)	3. Date 10-November-2016
4. Are you the cor	responding author?	Yes	√ No	Corresponding Author's Name Vivek Subbiah
Manuscript Title Phase I Dose Esc with Colorectal C		kinase VEGF I Cancer	nhibitor Reg	gorafenib and Anti-EGFR Antibody Cetuximab in Patients
6. Manuscript Ider 90380-INS-CMED	ntifying Number (if you kr D-RV-2	now it)		
Section 2.	The Work Under Co	onsideratio	n for Publ	ication
any aspect of the s statistical analysis,	ititution at any time recei ubmitted work (including	ve payment or but not limite	r services fron d to grants, d	n a third party (government, commercial, private foundation, etc.) for lata monitoring board, study design, manuscript preparation,
Section 3.	Relevant financial	activities o	utside the	submitted work.
of compensation clicking the "Add) with entities as descri	bed in the in: oort relations	structions. U hips that we	nether you have financial relationships (regardless of amount Use one line for each entity; add as many lines as you need by ere present during the 36 months prior to publication .
Section 4.	Intellectual Proper	ty Patent	s & Copyri	ghts
Do you have any	patents, whether planr	ned, pending	or issued, b	roadly relevant to the work? Yes Vo



Section 5.	
Section 5.	Relationships not covered above
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Dr. Fu has noth	ing to disclose.

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Section 1. Identifying Inform	nation				
Given Name (First Name) David	2. Surna Hong	me (Last Name)			3. Date 10-November-2016
4. Are you the corresponding author?	Yes	✓ No	Correspon Vivek Sub		nor's Name
5. Manuscript Title Phase I Dose Escalation Study of Multi-I with Colorectal Cancer and Advanced C	kinase VEG Cancer	F Inhibitor Re	gorafenib and	l Anti-EG	FR Antibody Cetuximab in Patients
6. Manuscript Identifying Number (if you kr 90380-INS-CMED-RV-2	now it)				
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The Work Under Co					
any aspect of the submitted work (including statistical analysis, etc.)?	ive paymen but not lim	t or services from nited to grants, o	m a third party data monitorin	(governm g board, s	nent, commercial, private foundation, etc.) for tudy design, manuscript preparation,
Are there any relevant conflicts of interest	est?	Yes ✓ No			
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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	bed in the	instructions. l	Jse one line fo	or each e	ntity; add as many lines as you need by
Are there any relevant conflicts of intere					First to passive in
If yes, please fill out the appropriate info	rmation b	elow.			
Name of Entity	Grant?		on-Financial Support?	Other?	Comments
Bayer				✓	Research support/Paid Consultant
Lilly				✓	Research support
Genentech				✓	Research support
LOXO				✓	Research support
Pfizer				✓	Research support
Amgen				\checkmark	Research support
Mirati				✓	Research support
lgnyta				1	Research support



Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Merck				√	Research support
Daichi-Sanko				✓	Research support
Eisai				✓	Research support
Baxter				1	Paid Consultant
OncoResponse				1	Ownership Interest
Section 4. Intellectual Propert Do you have any patents, whether plann				nt to the	work? ☐ Yes ✔ No
Section 5. Relationships not c		Marian San Canada			
Are there other relationships or activities potentially influencing, what you wrote in	that reac n the sub	lers could p mitted wor	perceive to have in k?	nfluence	d, or that give the appearance of
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✓ No other relationships/conditions/cire	cumstand	es that pre	sent a potential c	onflict o	finterest
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Dr. Hong reports other from Bayer, other Amgen, other from Mirati, other from Ign Baxter, other from OncoResponse, outsid	yta, othe	r from Mer	ck, other from Da	ner from I ichi-Sank	LOXO, other from Pfizer, other from to, other from Eisai, other from



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Janku



Section 1. Identifying Info	rmation			
1. Given Name (First Name) Filip	2. Surna Janku	me (Last Name)		3. Date 08-November-2016
4. Are you the corresponding author?	Yes	✓ No	Correspon Vivek Sub	nding Author's Name obiah
5. Manuscript Title Phase I Dose Escalation Study of Mult with Colorectal Cancer and Advanced	i-kinase VEG I Cancer	iF Inhibitor Reg	orafenib and	d Anti-EGFR Antibody Cetuximab in Patients
6. Manuscript Identifying Number (if you 90380-INS-CMED-RV-2	know it)			
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statistical analysis, etc.)? Are there any relevant conflicts of inte		Yes 🕢 No	ata monitorin	g board, study design, manuscript preparation,
Section 3. Relevant financia	l activities	outside the :	submitted	work.
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Are there any relevant conflicts of inte		res No		
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Section 4. Intellectual Property - Patenta & Commission	
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 apper potentially influencing, what you wrote in the submitted work?	earance of
✓ Yes, the following relationships/conditions/circumstances are present (explain below):	
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Jiang



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4. Are you the co	rresponding author?	☐ Yes ✓ No	Corresponding Author's Name Vivek Subbiah	
			orafenib and Anti-EGFR Antibody Cetu	ıximab in Patients
6. Manuscript Ide 90380-INS-CME	entifying Number (if you k D-RV-2	(now it)		
Section 2.	The Work Under C	Consideration for Publi	cation	
Are there any re	levant conflicts of inte	rest? Yes No	submitted work	
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Do you have an			roadly relevant to the work? Yes	√ No



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Johnson



Section 1. Identifying Inform	nation	
1. Given Name (First Name) Adrienne	2. Surname (Last Name) Johnson	3. Date 10-November-2016
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author's Name Vivek Subbiah
with Colorectal Cancer and Advanced C	Cancer	orafenib and Anti-EGFR Antibody Cetuximab in Patients
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Section 2. The Work Under C		
The Work Under Co	onsideration for Public	
Did you or your institution at any time rece any aspect of the submitted work (including statistical analysis, etc.)?	ive payment or services from but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for its monitoring board, study design, manuscript preparation,
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Do you have any patents, whether plant	ned, pending or issued, br	oadly relevant to the work? Yes Vo

Johnson



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	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
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Dr. Johnson rep	orts other from Foundation Medicine, outside the submitted work; .

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1. Given Name (Fi		SIMESTA	ne (Last Name)	3. Date
4. Are you the cor	responding author?	Yes	✓ No	Corresponding Author's Name Vivek Subbiah
with Colorectal C	alation Study of Multi-k Cancer and Advanced C	ancer	Inhibitor Rego	rafenib and Anti-EGFR Antibody Cetuximab in Patients
90380-INS-CMED	itifying Number (if you kn I-RV-2	ow it)		
Section 2.	The Work Under Co	onsiderati	ion for Public	ation
statistical analysis,	titution at any time receivable including	ve payment but not limi	or services from	a third party (government, commercial, private foundation, etc.) for a monitoring board, study design, manuscript preparation,
Section 3.	Relevant financial a	ctivities	outside the s	ubmitted work.
clicking the "Add	with entities as describ	oed in the i ort relation	nstructions. Use ships that were	ther you have financial relationships (regardless of amount point for each entity; add as many lines as you need by present during the 36 months prior to publication.
Section 4.	Intellectual Propert	y Paten	ts & Copyrig	nts
Do you have any p	patents, whether plann	ed, pendin	g or issued, bro	adly relevant to the work? Yes No
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	11	Noi	1 241	6



Section 5.	Relationships not covered above
Are there other repotentially influe	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
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Royalties: Funds are coming in to you or your institution due to your patent

Non-Financial Support: Examples include drugs/equipment

Khawaja



Section 1. Identifying Inform	nation	
Given Name (First Name) Muhammad	2. Surname (Last Name) Khawaja	3. Date 08-November-2016
4. Are you the corresponding author?	Yes No	Corresponding Author's Name Vivek Subbiah
5. Manuscript Title Phase I Dose Escalation Study of Multi- with Colorectal Cancer and Advanced		orafenib and Anti-EGFR Antibody Cetuximab in Patients
6. Manuscript Identifying Number (if you k 90380-INS-CMED-RV-2	now it)	
Section 2. The Work Under C		
The Work Under C	onsideration for Publi	cation
		n a third party (government, commercial, private foundation, etc.) for at a monitoring board, study design, manuscript preparation,
Are there any relevant conflicts of inter	est? Yes Vo	
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Section 3. Relevant financial	activities outside the	submitted work.
of compensation) with entities as descri	ribed in the instructions. U	nether 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 inter	est? Yes Vo	
Section 4. Intellectual Prope	rty Patents & Copyri	ghts
Do you have any patents, whether plan	nned, pending or issued, b	roadly relevant to the work? Yes V No



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	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	ationships/conditions/circumstances that present a potential conflict of interest
	anuscript 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.	Disclosure Statement
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Dr. Khawaja has	nothing to disclose.

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Kopetz 1



Section 1. Identifying Infor	mation			
Given Name (First Name) Scott	2. Surname (La Kopetz	st Name)	3. Date 07-Novemi	ber-2016
4. Are you the corresponding author?	☐ Yes ✓	No Correspo	onding Author's Name ubbiah	
Manuscript Title Phase I Dose Escalation Study of Mult with Colorectal Cancer and Advanced		bitor Regorafenib ar	nd Anti-EGFR Antibody Cetux	imab in Patients
6. Manuscript Identifying Number (if you 90380-INS-CMED-RV-2	know it)			
Section 2				
Section 2. The Work Under	Consideration f	or Publication		
any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of inte		o grants, data monitori	ng board, study design, manusc	ript preparation,
Section 3. Relevant financia	l activities outs	ide the submitte	d work.	
Place a check in the appropriate boxes of compensation) with entities as described clicking the "Add +" box. You should refer there any relevant conflicts of intelligence of the second control of the appropriate in the appropriate in the second control of the seco	ribed in the instrueport relationship rest? Yes	uctions. Use one line is that were present No	for each entity; add as many	lines as you need by
Name of Entity	Grant? Perso		Other? Comments	
Amgen				
Array				
Bayer				
Genentech				
Molecular Match			✓ Ownership	
Taiho				



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Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo
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Dr. Kopetz reports personal fees from Amgen, personal fees from Array, personal fees from Bayer, personal fees from Genentech, other from MolecularMatch, personal fees from Taiho, outside the submitted work; .
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Section 1.	Identifying Inform	mation			
1. Given Name (F Hui	irst Name)	2. Surname Liu	e (Last Name)		Date -November-2016
4. Are you the co	rresponding author?	Yes	✓ No	Corresponding Author's Name Vivek Subbiah	
			Inhibitor Reg	orafenib and Anti-EGFR Antiboo	dy Cetuximab in Patients
6. Manuscript Ide 90380-INS-CME	entifying Number (if you k D-RV-2	now it)			
Section 2.	The Work Under C	Onsideratio	on for Publi	cation	
	stitution at any time rec	eive payment o	or services from	a third party (government, comme ata monitoring board, study design	
statistical analysis	, etc.)?		M <u>-2</u>	ica monitoring board, study design	i, manuscript preparation,
Are there any re	levant conflicts of inter	est? Ye	es ✓ No		
Section 3.	Relevant financia	activities o	outside the	submitted work.	
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Section 4.	Intellectual Prope	rty Paten	ts & Copyri	ghts	
Do you have any	y patents, whether plar	nned, pendin	g or issued, b	roadly relevant to the work?	Yes ✓ No



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Yes, the follo	owing relationships/conditions/circumstances are present (explain below):
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I don't have cor	nflict of interest with this submission.

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Meric-Bernstam 1



Section 1. Identifying Inform	nation			A
1. Given Name (First Name) Funda	2. Surname (Last Name) Meric-Bernstam		3. Date 07-November-2016	
4. Are you the corresponding author?	Yes ✓ No	Corresponding Auth Vivek Subbiah	nor's Name	
Manuscript Title Phase I Dose Escalation Study of Multi-I with Colorectal Cancer and Advanced C	kinase VEGF Inhibitor Rego Cancer	orafenib and Anti-EG	FR Antibody Cetuximab in Patients	
6. Manuscript Identifying Number (if you kr 90380-INS-CMED-RV-2	now it)			
Section 2				
Section 2. The Work Under Co	onsideration for Publi	cation		
Did you or your institution at any time receing any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of interests there are supported by the submitted work (including statistical analysis, etc.)?	but not limited to grants, da	ata monitoring board, s	tudy design, manuscript preparation,	_
Relevant financial	activities outside the s	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. Use oort relationships that werest?	se one line for each e	ntity; add as many lines as you need by	
Name of Entity	Grant	n-Financial other?	Comments	
Novartis; AstraZeneca; Taiho; Genentech; Calithera; Debiopharma; Bayer; Aileron; ounce; CytoMx, Effective Pharma; Zymeworks; Puma				
Clearlight Diagnostics			Paid consultant	
Genentech; Inflection Biosciences; Pieris; Darwin Health; Grail			Advisory board	



Section 4.	Intellectual Property Patents & Copyrights
Do you have a	ny patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo
Section 5.	Relationships not covered above
Are there othe potentially infl	r relationships or activities that readers could perceive to have influenced, or that give the appearance of uencing, what you wrote in the submitted work?
Yes, the fol	lowing relationships/conditions/circumstances are present (explain below):
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Jounce; CytoN	stam reports grants from Novartis; AstraZeneca; Taiho; Genentech; Calithera; Debiopharma; Bayer; Aileron; lx, Effective Pharma; Zymeworks; Puma, personal fees from Clearlight Diagnostics, personal fees from flection Biosciences; Pieris; Darwin Health; Grail, outside the submitted work; .

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Naing



Section 1. Identifying Info	ormation	
Given Name (First Name) Aung	2. Surname (Last Name) Naing	3. Date 08-November-2016
4. Are you the corresponding author?	Yes No	Corresponding Author's Name Vivek Subbiah
5. Manuscript Title Phase I Dose Escalation Study of Mu with Colorectal Cancer and Advance		orafenib and Anti-EGFR Antibody Cetuximab in Patients
6. Manuscript Identifying Number (if yo 90380-INS-CMED-RV-2	u know it)	
Section 2. The Week Hode	r Consideration for Publi	
Section 3.		
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Overman



Section 1. Identifying Inform	ation		
Given Name (First Name) Michael	2. Surname (Last Name) Overman	3. Date 08-Nove	ember-2016
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author's Name Vivek Subbiah	
5. Manuscript Title Phase I Dose Escalation Study of Multi-k with Colorectal Cancer and Advanced Co	ancer	orafenib and Anti-EGFR Antibody Cet	uximab in Patients
6. Manuscript Identifying Number (if you kn 90380-INS-CMED-RV-2	ow it)		
Section 2. The Work Under Co	onsideration for Public		
Did you or your institution at any time receivany aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of interest	ve payment or services from but not limited to grants, da	a third party (government, commercial, r	orivate foundation, etc.) for uscript preparation,
Section 3. Relevant financial a	activities outside the s	ubmitted work.	
Place a check in the appropriate boxes in of compensation) with entities as describelicking the "Add +" box. You should report there any relevant conflicts of interests.	ped in the instructions. Us ort relationships that were	e one line for each entity; add as mar	ny lines as you need by
Section 4. Intellectual Propert	y Patents & Copyrig	hts	
Do you have any patents, whether plann			✓ No



Section 5. Relationships not covered above
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potentially influencing, what you wrote in the submitted work?
Yes, the following relationships/conditions/circumstances are present (explain below):
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Piha-Paul



Section 1. Identifying Inforn	nation	A PARKETER DELICATION OF THE PARKET OF THE P
1. Given Name (First Name) Sarina	2. Surname (Last Name) Piha-Paul	3. Date 07-November-2016
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Vivek Subbiah
5. Manuscript Title Phase I Dose Escalation Study of Multi- with Colorectal Cancer and Advanced (orafenib and Anti-EGFR Antibody Cetuximab in Patients
6. Manuscript Identifying Number (if you ki 90380-INS-CMED-RV-2	now it)	
Section 2. The Work Under C	onsideration for Publi	cation
		a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
Are there any relevant conflicts of inter-	est?	
Section 3. Relevant financial	activities outside the	submitted work.
of compensation) with entities as descr	ibed 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 interest	est? Yes No	
Section 4. Intellectual Prope	rty Patents & Copyri	ghts and the same of the same
Do you have any patents, whether plan	ned, pending or issued, b	roadly relevant to the work? Yes No



Section 5.	
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?
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At the time of m On occasion, jou	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.	Disclosure Statement
Based on the ab below.	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Piha-Paul ha	s nothing to disclose.

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patent

Schrock



Section 1. Identifying Inform	nation			
1. Given Name (First Name) Alexa	2. Surname (L Schrock	ast Name)		3. Date 08-November-2016
4. Are you the corresponding author?	Yes ✓	- STATE OF THE PARTY OF THE PAR	ponding Auth Subbiah	or's Name
5. Manuscript Title Phase I Dose Escalation Study of Multi- with Colorectal Cancer and Advanced		ibitor Regorafenib	and Anti-EGF	FR Antibody Cetuximab in Patients
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The Work Under C	onsideration	for Publication		
any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of inter If yes, please fill out the appropriate inf Excess rows can be removed by pressin Name of Institution/Company	est? Yes ormation below g the "X" butto	No r. If you have more to n. Sonal Non-Finance	than one ent	ity press the "ADD" button to add a row
undation Medicine, Inc.		es Support		Full time employee and stock
Section 2				ownership.
Section 3. Relevant financial	activities out	side the submitt	ed work.	
Place a check in the appropriate boxes of compensation) with entities as descr clicking the "Add +" box. You should re Are there any relevant conflicts of inter-	ibed in the insti port relationshi est? 🗸 Yes	ructions. Use one lir ps that were prese No	ne for each ei	ntity; add as many lines as you need by
Name of Entity	Grant	sonal Non-Financ	Otner	Comments
		es Support		

Schrock



Section 4. Intellectual Property Patents & Copyrights
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo
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Dr. Schrock reports personal fees from Foundation Medicine, Inc., during the conduct of the study; personal fees from Foundation Medicine, Inc., outside the submitted work; .

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4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Vivek Subbiah
5. Manuscript Title Phase I Dose Escalation Study of Multi-k with Colorectal Cancer and Advanced C		orafenib and Anti-EGFR Antibody Cetuximab in Patients
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Name of Entity	Grant	on-Financial Other? Comments
Foundation Medicine		Employee and shareholder
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Do you have any patents, whether plant	ned, pending or issued, b	roadly relevant to the work? Yes V No



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Tsimberidou 1



Given Name (First Name) Apostolia M							
	2. Surnam Tsimberio	ne (Last Name dou	<u>e)</u>		3. Date 10-November-2016		
4. Are you the corresponding author?	Yes	✓ No		Corresponding Author's Name Vivek Subbiah			
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Tsimberidou



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	nd Feedback
Evaluation a	nd Feedback //www.icmje.org/cgi-bin/feedback to provide feedback on your experience with completing this form.

TREND Statement Checklist

Paper Item		Descriptor	Repo	rted?
Section/ Topic	No			Pg#
Title and Abst	ract			
Title and	1	Information on how unit were allocated to interventions	V	3
Abstract		Structured abstract recommended	V	3
		Information on target population or study sample		3
Introduction				
Background	2	Scientific background and explanation of rationale	1	4
•		Theories used in designing behavioral interventions		4
Methods				-
Participants	3	Eligibility criteria for participants, including criteria at different levels in		T
2.00		recruitment/sampling plan (e.g., cities, clinics, subjects)	1	12
		Method of recruitment (e.g., referral, self-selection), including the		. 7-
		sampling method if a systematic sampling plan was implemented		10
		Recruitment setting	1	12
		Settings and locations where the data were collected		12
Interventions	4	Details of the interventions intended for each study condition and how		
		and when they were actually administered, specifically including:	1	12
		Content: what was given?	~	12
		O Delivery method: how was the content given?	/	12
		 Unit of delivery: how were the subjects grouped during delivery? 	1/	12 1
		O Deliverer: who delivered the intervention?		12.13
		 Setting: where was the intervention delivered? 		ا ا
		 Exposure quantity and duration: how many sessions or episodes or 	/	
		events were intended to be delivered? How long were they intended to last?		12,
		Time span: how long was it intended to take to deliver the	1	15 (
		intervention to each unit?		12,1
Ohiostivos	-	Activities to increase compliance or adherence (e.g., incentives)		12,1
Objectives	6	Specific objectives and hypotheses	1	12,1
Outcomes	6	Clearly defined primary and secondary outcome measures		12
		 Methods used to collect data and any methods used to enhance the quality of measurements 		12
		Information on validated instruments such as psychometric and biometric	N // A	1
		properties	10/1	J
Sample Size	7	 How sample size was determined and, when applicable, explanation of any 	1	17
		interim analyses and stopping rules		12
Assignment	8	 Unit of assignment (the unit being assigned to study condition, e.g., 	1	
Method		individual, group, community)		12
		Method used to assign units to study conditions, including details of any	/	1 1
		restriction (e.g., blocking, stratification, minimization)		10
		Inclusion of aspects employed to help minimize potential bias induced due	/	(7
		to non-randomization (e.g., matching)		14

TREND Statement Checklist

9	 Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed. 	N	A
10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	NIF	
	 If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis) 	2/	A
11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data		14
	analyses and adjusted analysis		14,
			14,1
	Statistical software or programs used		16
			111
12	Flow of participants through each stage of the study; enrollment	T	Γ
		/	7 -
			Lo

		/	/
			6
	Assignment: the numbers of participants assigned to a study condition	~	/
	 Allocation and intervention exposure: the number of participants 		0
	assigned to each study condition and the number of participants	/	6
			,
		1/	6
			1
		/	/
			6
		/	- (
	reasons		6
13	Dates defining the periods of recruitment and follow-up		1
14			6
	study condition	/	19
			
	disease prevention research	1/	19
		,	<u> </u>
	and by study condition		19
	Comparison between study population at baseline and target population	/	10
			1
15	of interest ·		[]
15			141
	10 11 12	those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed. 10 Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis) Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis Methods for imputing missing data, if used Statistical software or programs used 12 Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study Assignment: the numbers of participants assigned to a study condition Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition Analysis: the number of participants included in or excluded from the main analysis, by study condition Description of protocol deviations from study as planned, along with reasons Dates defining the periods of recruitment and follow-up Baseline demographic and clinical characteristics of participants in each study condition Baseline characteristics for each study condition relevant to specific disease prevention research Baseline comparisons of those lost to follow-up and those retained, overall	those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed. 10 Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis) Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis Methods for imputing missing data, if used Statistical software or programs used 12 Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study Assignment: the numbers of participants assigned to a study condition Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition Analysis: the number of participants included in or excluded from the main analysis, by study condition Description of protocol deviations from study as planned, along with reasons Dates defining the periods of recruitment and follow-up Baseline characteristics for each study condition relevant to specific disease prevention research Baseline comparisons of those lost to follow-up and those retained, overall

TREND Statement Checklist

Numbers	16	Number of participants (denominator) included in each analysis for each		
analyzed		study condition, particularly when the denominators change for different	1	ile
		outcomes; statement of the results in absolute numbers when feasible		, 171
		 Indication of whether the analysis strategy was "intention to treat" or, if 		1,
		not, description of how non-compliers were treated in the analyses		141
Outcomes and	17	For each primary and secondary outcome, a summary of results for each		
estimation		estimation study condition, and the estimated effect size and a confidence	/	71
		interval to indicate the precision	Li	$ \alpha $
		Inclusion of null and negative findings	NA	-
		Inclusion of results from testing pre-specified causal pathways through	111	\wedge
		which the intervention was intended to operate, if any	10/	
Ancillary	18	Summary of other analyses performed, including subgroup or restricted	15	
analyses		analyses, indicating which are pre-specified or exploratory	NII	+
Adverse events	19	Summary of all important adverse events or unintended effects in each	1	
		study condition (including summary measures, effect size estimates, and	1/	27
		confidence intervals)		~0
DISCUSSION				
Interpretation	20	Interpretation of the results, taking into account study hypotheses,		
		sources of potential bias, imprecision of measures, multiplicative analyses,	/	14 11
		and other limitations or weaknesses of the study		7-11
		Discussion of results taking into account the mechanism by which the		
		intervention was intended to work (causal pathways) or alternative	/	4 1
		mechanisms or explanations		7-11
		Discussion of the success of and barriers to implementing the intervention,	7	
		fidelity of implementation	1	4-1
		Discussion of research, programmatic, or policy implications	/	6 10
Generalizability	21	Generalizability (external validity) of the trial findings, taking into account		4-11
,		the study population, the characteristics of the intervention, length of		1
		follow-up, incentives, compliance rates, specific sites/settings involved in	1	4-11
		the study, and other contextual issues		
Overall	22	General interpretation of the results in the context of current evidence	/	1
Evidence		and current theory		4-1
AND THE PROPERTY OF THE PROPER		1		

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. American Journal of Public Health, 94, 361-366. For more information, visit: http://www.cdc.gov/trendstatement/