Date:	12/2/2022	
Your Name:	Asghar Abdoli	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMI-2022-070464	

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial planning of the work	
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	⊠ None	Click the tab key to add additional rows.
		Time frame: past 36 month	ns
2	Grants or contracts from any entity (if not indicated in item #1 above).	□	
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	⊠ None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None I am the founder and the scientific director of Amirabad Virology Lab and the only shareholder of this laboratory. I serve as a faculty member of the Pasteur Institute of Iran. Moreover, I was a project consultant for the PastoCoAd vaccine project, which was initiated after the BIV1- CovIran vaccine project.	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\boxtimes]$	I certify that I have answered every question and have not altered the wording of any of the questions on this form.		

Date:	6/7/2022	
Your Name:	Erfan Ghasemi	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BM1-2022-070464	

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		Time frame: past 36 months	
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ None	
3	Royalties or licenses	None	

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4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None □ □ □ □ □ □	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\boxtimes]$	I certify that I have	answered every question and have not altered the wo	rding of any of the questions on this form.

Date:	6/7/2022	
Your Name:	Farzin Khorvash	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscrint Number (if known):	BM1-2022-070464	

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		Time frame: past 36 months	
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ None	
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None	

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11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None □ □ □ □ □ □	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\boxtimes]$	I certify that I have	answered every question and have not altered the wo	rding of any of the questions on this form.

Date:	5/24/2022	
Your Name:	Hamed Hosseini	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMJ-2022-070464	

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		Time frame: Since the initial planning o	of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	None As manager of the Clinical Trial Center (CTC), an academic CRO affiliated with Tehran University of Medical Sciences, Tehran, Iran, I was responsible for the conduct and monitoring of clinical trials. Time frame: past 36 months	Click the tab key to add additional rows.
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ None	
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☑ None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	 None I was a non-voting member of DSMB. It was mandated by national regulatory. 	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\boxtimes]$	I certify that I have answered every question and have not altered the wording of any of the questions on this form.		

Hamed Hosseini May 24, 2022

Hossein

Date:	6/7/2022	
Your Name:	Katayoun Vahdat	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BM1-2022-070464	

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3	Royalties or licenses	None	

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4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None	

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11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None □ □ □ □ □ □	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\boxtimes]$	I certify that I have	answered every question and have not altered the wo	rding of any of the questions on this form.

Date:	6/7/2022	
Your Name:	Keyvan Koohgir	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscrint Number (if known):	BM1-2022-070464	

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3	Royalties or licenses	None	

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4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None	

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11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None □ □ □ □ □ □	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\boxtimes]$	I certify that I have	answered every question and have not altered the wo	rding of any of the questions on this form.

Date:	6/7/2022	
Your Name:	Maryam Amini Pouya	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMJ-2022-070464	

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		Time frame: past 36 months	
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ None	
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
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11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None □ □ □ □ □ □	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\boxtimes]$	I certify that I have	answered every question and have not altered the wo	rding of any of the questions on this form.

Date:	12/2/2022	
Your Name:	Minoo Mohraz	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscrint Number (if known):	RM1-2022-070464	

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		Time frame: Since the initial planning o	of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	None As the principal investigator, I received funding for project administration from Shifa-Pharmed Industrial Group (grant number 63971). Time frame: past 36 monther	Click the tab key to add additional rows.
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ None	
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None □ □ □ □ □ □	

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11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\bowtie]$	I certify that I have	answered every question and have not altered the wo	ording of any of the questions on this form.

Date:	6/7/2022	
Your Name:	Mohammad-Reza Malekpour	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMJ-2022-070464	

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		Time frame: past 36 month	IS
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ None	
3	Royalties or licenses	None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None	

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11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None □ □ □ □ □ □	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\boxtimes]$	I certify that I have	answered every question and have not altered the wo	rding of any of the questions on this form.

Date:	5/31/2022	
Your Name:	Mohammadreza Salehi	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMJ-2022-070464	

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		Time frame: past 36 months	
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ None	
3	Royalties or licenses	☑ None □ □ □ □	

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4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	Image: None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\bowtie]$	I certify that I have	answered every question and have not altered the wo	rding of any of the questions on this form.

Date:	6/1/2022	
Your Name:	Mohsen Abbasi-Kangevari	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMJ-2022-070464	

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Time frame: Since the initial planning of the work	
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	☑ None	Click the tab key to add additional rows.
		Time frame: past 36 months	
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ None	
3	Royalties or licenses	☑ None □ □ □ □	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☑ None □ □ □ □ □ □	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None	
6	Payment for expert testimony	⊠ None	
7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	Image: None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	⊠ None	

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11	Stock or stock options	⊠ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	⊠ None	
13	Other financial or non-financial interests	⊠ None	
Plea	Please place an "X" next to the following statement to indicate your agreement:		
$[\bowtie]$	I certify that I have	answered every question and have not altered the wo	rding of any of the questions on this form.

Date:	6/7/2022	
Your Name:	Mohsen Moghadami	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
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Date:	6/7/2022
Your Name:	Negar Rezaei
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak
Manuscript Number (if known):	BMI-2022-070464

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Date:	6/6/2022	
Your Name:	Payam Tabarsi	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMI-2022-070464	

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7	Support for attending meetings and/or travel	⊠ None	
8	Patents planned, issued or pending	⊠ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	⊠ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None I was the principal investigator of another vaccine project (spikogen)	

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Date:	6/7/2022	
Your Name:	Rozita Khodashahi	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMJ-2022-070464	

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Date:	6/7/2022	
Your Name:	Sahar Saeedi Moghaddam	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
Manuscript Number (if known):	BMJ-2022-070464	

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Date:	6/1/2022	
Your Name:	Seyyed-Hadi Ghamari	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
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Date:	6/7/2022	
Your Name:	Yasaman Ghabdian	
Manuscript Title:	Efficacy and Safety of an Inactivated Virus-Particle Vaccine for SARS-CoV-2, BIV1-CovIran: Findings from a Randomised, Placebo-Controlled, Double-Blind, Multicenter Phase III Clinical Trial amid the Delta Variant Peak	
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