Section and Topic	Item #	Descriptor	Reported on Page #
Title and Abstract	1	How participants were allocated to interventions (eg "random allocation," "randomized" or "randomly assigned")	1, 4
Introduction			
Background	2	Scientific background and explanation of rationale	6-7
<i>Methods</i> Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected	18-19
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	19
Objectives	5	Specific objectives and hypotheses	7
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg multiple observations, training of assessors)	19-21
Sample Size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	NA
Randomization			
Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification)	NA
Allocation concealment	9	Method used to implement the random allocation sequence (eg numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned	NA
Implementation	10	Who generated the allocation sequence, who enrolled the participants, and who assigned participants to their groups	NA
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated	Not provided
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	21-22
Results Participant flow	13	Flow or participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons	Figure 1
Recruitment	14	Dates defining the periods of recruitment and follow-up	18-19
Baseline data	15	Baseline demographic and clinical characteristics of each group	Table 1
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (eg, 10/20, not 50%)	Figure 1
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg 95% confidence interval)	8-14, Figures 2-6, Supplemental eResults
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory	NA
Adverse events	19	All important adverse events or side effects in each intervention group	13-14, Table 2
Discussion Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources or potential bias or imprecision, and the dangers associated	15-17
Conoralizability	21	with multiplicity of analyses and outcomes	17
Generalizability	21	Generalizability (external validity) of the trial findings	17 17
Overall evidence	22	General interpretation of the results in the context of current evidence	1/

CONSORT	checklist of items	to include when	reporting a r	andomized trial
001100111				



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Section 1. Identifying Infor	mation	
1. Given Name (First Name) Michael P.	2. Surname (Last Name) Whyte	3. Date 08-October-2015
4. Are you the corresponding author?	✓ Yes No	
5. Manuscript Title Asfotase Alfa Therapy for Children wi	th Hypophosphatasia	

6. Manuscript Identifying Number (if you know it)

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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
Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees	Non-Financial Support?	Other?	Comments	
Alexion Pharmaceuticals, Inc.	\checkmark		\checkmark		Research grants and study drug	

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Are there any relevant conflicts of interest? Yes No

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support	Other?	Comments	
Alexion Pharmaceuticals, Inc.		\checkmark			Honoraria and travel support	



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

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Dr. Whyte reports grants and non-financial support from Alexion Pharmaceuticals, Inc., during the conduct of the study; honoraria and travel support from Alexion Pharmaceuticals, Inc., outside the submitted work; .

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Section 1. Identifying Info	rmation	
1. Given Name (First Name) Katherine L.	2. Surname (Last Name) Madson	3. Date 08-October-2015
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
5. Manuscript Title Asfotase Alfa Therapy for Children wi	th Hypophosphatasia	

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.)?

Are there any relevant conflicts of interest?	\checkmark	Yes	N	١o
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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?	Other?	Comments	
Alexion Pharmaceuticals, Inc.	\checkmark		\checkmark		Research grants and study drug	

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Are there any relevant conflicts of interest? Yes No

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Alexion Pharmaceuticals, Inc.		\checkmark			Honoraria and travel support	



Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Madson reports grants and non-financial support from Alexion Pharmaceuticals, Inc to Shriners Hospitals for Children during the conduct of the study; honoraria and travel support from Alexion Pharmaceuticals, Inc., outside the submitted work.

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Section 1.	Identifying Infor	mation	
1. Given Name (Fi Dawn	rst Name)	2. Surname (Last Name) Phillips	3. Date 27-August-2015
4. Are you the corresponding author?		Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
5. Manuscript Titl Asfotase Alfa Th	e erapy for Children wit	h Hypophosphatasia	
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Are there any relevant conflicts of interest?	\checkmark	Yes	N	١o
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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support	Other?	Comments	
Alexion Pharmaceuticals, Inc.		\checkmark			Served as consultant	

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 Given Name (First Name) Amy L. Are you the corresponding auth 		3. Date 27-August-2015 onding Author's Name I P. Whyte
5. Manuscript Title Asfotase Alfa Therapy for Child	en with Hypophosphatasia	

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Are there any relevant conflicts of interest?	✓	Yes		No
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Shriners Hospitals for Children has received research grants from Alexion Pharmaceuticals, Inc., to support Ms. Reeves for the submitted work.

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1. Given Name (First Name) William H.	2. Surname (Last Name) McAlister	3. Date 27-August-2015
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
5. Manuscript Title Asfotase Alfa Therapy for Children	vith Hypophosphatasia	

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🖌 No

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

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



Section 1.	Identifying Infor	mation	
1. Given Name (Fi Amy	rst Name)	2. Surname (Last Name) Yakimoski	3. Date 27-August-2015
4. Are you the cor	responding author?	Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
5. Manuscript Titl Asfotase Alfa Th		h Hypophosphatasia	

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.

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	\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	\checkmark	No
	1 1		•	



Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

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

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Ms. Yakimoski has nothing to disclose.

Evaluation and Feedback



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Section 1. Identifying Infor	mation	
1. Given Name (First Name) Karen E.	2. Surname (Last Name) Mack	3. Date 27-August-2015
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
5. Manuscript Title Asfotase Alfa Therapy for Children wit	h Hypophosphatasia	

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.)?

Are there any relevant conflicts of interest?	✓	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 rov	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	
Alexion Pharmaceuticals, Inc.	\checkmark					

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? \Box Yes \checkmark 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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Shriners Hospitals for Children has received research grants from Alexion Pharmaceuticals, Inc., to support Ms. Mack for the submitted work.

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Section 1. Identifying Infor	mation	
1. Given Name (First Name) Kimberly	2. Surname (Last Name) Hamilton	3. Date 27-August-2015
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
5. Manuscript Title Asfotase Alfa Therapy for Children wi	h Hypophosphatasia	

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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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	
Alexion Pharmaceuticals, Inc.		\checkmark			Received honorarium from Alexion	

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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Ms. Hamilton reports receiving honorarium and travel support from Alexion Pharmaceuticals, Inc., outside the submitted work.

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Section 1. Identifying Info	rmation	
 Given Name (First Name) Kori Are you the corresponding author? 	2. Surname (Last Name) Kagan Yes 🖌 No	3. Date 27-August-2015 Corresponding Author's Name
 Manuscript Title Asfotase Alfa Therapy for Children w Manuscript Identifying Number (if yo 		Michael P. Whyte

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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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



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Dr. Kagan has nothing to disclose.

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Section 1. Identifying Inf	ormation	
1. Given Name (First Name) Kenji	2. Surname (Last Name) Fujita	3. Date 19-October-2015
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
5. Manuscript Title Asfotase Alfa Therapy for Children v	vith Hypophosphatasia	

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Are there any relevant conflicts of interest?	🖌 Ye	s	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 <mark>?</mark>	Other?	Comments	
Alexion Pharmaceuticals, Inc.		\checkmark			Received compensation and has stock options as employee of Alexion Pharmaceuticals, Inc.	

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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
Alexion Pharmaceuticals, Inc.		\checkmark			Received compensation and has stock options as employee of Alexion Pharmaceuticals, Inc.



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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Dr. Fujita reports receiving compensation and having stock options as an employee of Alexion Pharmaceuticals, Inc., during the conduct of the study; and receiving compensation and having stock options as an employee of Alexion Pharmaceuticals, Inc., outside the submitted work.

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Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

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 Penalties: Funds are coming in to you eryour institution due to you



rmation	
2. Surname (Last Name) Thompson	3. Date 27-August-2015
Yes 🗸 No	Corresponding Author's Name Michael P. Whyte
ith Hypophosphatasia	
	Thompson

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.)?

Are there any relevant conflicts of interest?	🖌 Ye	s	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?	Other?	Comments	
Alexion Pharmaceuticals, Inc.		\checkmark			Received compensation and has stock options as employee of Alexion Pharmaceuticals, Inc.	

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.

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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 V No

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

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

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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Thompson reports receiving compensation and having stock options as an employee of Alexion Pharmaceuticals, Inc., during the conduct of the study; and receiving compensation and having stock options as an employee of Alexion Pharmaceuticals, Inc., outside the submitted work.

Evaluation and Feedback



Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

1. Identifying information.

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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 In	formation	
1. Given Name (First Name) Scott	2. Surname (Last Name) Moseley	3. Date 27-August-2015
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
5. Manuscript Title Asfotase Alfa Therapy for Children	with Hypophosphatasia	

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest?	🖌 Yes	No
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Are there any relevant conflicts of interest? Yes 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 Ves

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Mr. Moseley reports receiving compensation as an employee of Alexion Pharmaceuticals, Inc., during the conduct of the study; and receiving compensation as an employee of Alexion Pharmaceuticals, Inc., outside the submitted work.

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Section 1.	Identifying Infor	mation			
1. Given Name (Fi Tatjana	rst Name)	2. Surname (Last Name) Odrljin	3. Date 27-August-2015		
Are you the corresponding author? Yes 🖌 No		Yes 🖌 No	Corresponding Author's Name Michael P. Whyte		
5. Manuscript Title Asfotase Alfa Th		th Hypophosphatasia			
6. Manuscript Ide	ntifying Number (if you	know it)			

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

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Alexion Pharmaceuticals, Inc.		\checkmark			Received compensation as an employee of Alexion Pharmaceuticals, Inc.	
Alexion Pharmaceuticals, Inc.		\checkmark			Has patent pending with Alexion Pharmaceuticals, Inc. for asfotase alfa	

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Dr. Odrljin reports receiving compensation as an employee of Alexion Pharmaceuticals, Inc. and has a patent pending with Alexion for asfotase alfa, both during the conduct of the study; and receiving compensation as an employee of Alexion Pharmaceuticals, Inc., outside the submitted work.



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

325 6

5.



Section 1. Identifying Information

1. Given Name (First Name) Cheryl R.	2. Surname (Last Name) Greenberg	3. Date 27-August-2015
4. Are you the corresponding author?	Yes 🖌 No	Corresponding Author's Name Michael P. Whyte
 Manuscript Title Asfotase Alfa Therapy for Children wit Manuscript Identifying Number (if you I 		where it is the summarized state of the summarized state of the summarized state state of the summarized state of the summari

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Are there any relevant conflicts of interest? Yes No

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Name of Institution/Company	Grant?	Personal Fees	Non-Financial Support [?]	Other?	Comments	
Alexion Pharmaceuticals, Inc.		\checkmark			Study investigator for Alexion Pharmaceuticals, Inc.	

Section 3. Relevant financial activities outside the submitted work.

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If yes, please fill out the appropriate information below.

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Alexion Pharmaceuticals, Inc.		✓		Received honoraria and travel support from Alexion Pharmaceuticals, Inc.	



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Dr. Greenberg reports personal fees as Study Investigator from Alexion Pharmaceuticals, Inc., during the conduct of the study; and receiving honoraria and travel support from Alexion Pharmaceuticals, Inc., outside the submitted work.

PPNN

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No No

Evaluation and Feedback