

**Online supplemental material:****Appendix I: Results of answers to all closed-ended questions, according to parental demographics**

Category 1: Demographics	Total n = 108	ProP n = 43	PNeo n = 35	PAX n = 30
1.1 Gender:	68 Female; 40 Male	25 Female; 18 Male	22 Female; 13 Male	21 Female; 9 Male
1.2 Age in years (mean, $\pm$ SD):	Women: 33 ( $\pm$ 4) Men: 35 ( $\pm$ 6)	Women: 32 ( $\pm$ 3) Men: 33 ( $\pm$ 4)	Women: 33 ( $\pm$ 5) Men: 37 ( $\pm$ 5)	Women: 35 ( $\pm$ 5) Men: 37 ( $\pm$ 8)
1.3 Nationality:	98 German; 1 Italian; 1 Ugandan; 1 Croatian; 1 Romanian; 3 Bosnian-Herzegovinian; 1 Dutch; 2 Russian and German	40 German; 1 Italian; 1 Croatian; 1 Bosnian-Herzegovinian;	30 German; 1 Romanian; 2 Bosnian-Herzegovinian; 1 Dutch; 1 Russian and German	28 German; 1 Ugandan; 1 Russian and German
1.4 Religion:	60 Christians; 3 Orthodox; 43 no religion or don't care about religion; 2 invalid answers	22 Christians; 0 Orthodox; 20 no religion or don't care about religion; 1 invalid answers	25 Christians; 1 Orthodox; 9 no religion or don't care about religion; 0 invalid answers	13 Christians; 2 Orthodox; 14 no religion or don't care about religion; 1 invalid answers
1.5 Highest education:	38 Vocational training; 62 University degree/PhD; 8 Other	9 Vocational training; 33 University degree/PhD; 1 Other	12 Vocational training; 20 University degree/PhD; 3 Other	17 Vocational training; 9 University degree/PhD; 4 Other

<b>Main text: a) Trust in physicians</b>			Number of evaluable answers / cannot judge / missings
Written on questionnaire: Category 2: "The following questions relate to your general attitude towards medicine and your physicians"			
2.1 "I believe, my physicians to make the right decisions for me and my health. "	<u>88% agreed</u> ProP: 98% vs. PNeo: 77% vs. PAX: 87% 88% females vs. 88% males 87% religious vs. 93% non-religious 92% $\geq$ university degree vs. 85% else	<u>8% disagreed</u> ProP: 0% vs. PNeo: 20% vs. PAX: 7% 9% females vs. 8% males 10% religious vs. 2% non-religious 7% $\geq$ university degree vs. 10% else	104 / 3 / 1
2.2 "I always get a second medical opinion before I give my consent to treatment."	<u>27% agreed</u> ProP: 26% vs. PNeo: 34% vs. PAX: 20% 27% females vs. 28% males 28% religious vs. 21% non-religious 24% $\geq$ university degree vs. 31% else	<u>71% disagreed</u> ProP: 72% vs. PNeo: 63% vs. PAX: 80% 72% females vs. 70% males 70% religious vs. 78% non-religious 74% $\geq$ university degree vs. 67% else	106 / 2 / 0
2.3 "I prefer alternative medical methods to conventional medicine."	<u>24% agreed</u> ProP: 12% vs. PNeo: 29% vs. PAX: 37% 31% females vs. 13% males 20% religious vs. 27% non-religious 15% $\geq$ university degree vs. 39%	<u>72% disagreed</u> ProP: 79% vs. PNeo: 71% vs. PAX: 63% 68% females vs. 80% males 75% religious vs. 71% non-religious 81% $\geq$ university degree vs. 62% else	104 / 4 / 0

<b>Main text: a) Trust in physicians and b) medical interventions (in general)</b> Written on questionnaire: Category 3: "The following questions relate to your attitude towards the physicians who would treat your child."			Number of evaluable answers / cannot judge / missings
3.1 "I would rely completely on the opinion and decisions of my child's physicians."	<u>81% agreed</u> ProP: 86% vs. PNeo: 74% vs. PAX: 80% 79% females vs. 83% males 82% religious vs. 80% non-religious 76% ≥ university degree vs. 92% else	<u>17% disagreed</u> ProP: 12% vs. PNeo: 23% vs. PAX: 17% 16% females vs. 18% males 15% religious vs. 18% non-religious 21% ≥ university degree vs. 5% else	105 / 1 / 2
3.2 "I would be more critical of the physician who treats my child, than I would be if it was my own treatment/physician."	<u>76% agreed</u> ProP: 63% vs. PNeo: 80% vs. PAX: 90% 77% females vs. 75% males 68% religious vs. 84% non-religious 74% ≥ university degree vs. 77% else	<u>22% disagreed</u> ProP: 35% vs. PNeo: 20% vs. PAX: 7% 22% females vs. 23% males 28% religious vs. 16% non-religious 23% ≥ university degree vs. 23% else	106 / 1 / 1
3.3 "Before the physicians start to treat my child, I always want to know what they want to do and why."	<u>95% agreed</u> ProP: 95% vs. PNeo: 94% vs. PAX: 97% 96% females vs. 95% males 95% religious vs. 96% non-religious 98% ≥ university degree vs. 90% else	<u>4% disagreed</u> ProP: 2% vs. PNeo: 6% vs. PAX: 3% 3% females vs. 5% males 5% religious vs. 2% non-religious 2% ≥ university degree vs. 8% else	107 / 1 / 0
3.4 "I always would like to be informed before my child is treated. I always want to be able to give my consent, even if this delay could reduce the success of the treatment."	<u>50% agreed</u> ProP: 51% vs. PNeo: 46% vs. PAX: 53% 49% females vs. 53% males 43% religious vs. 59% non-religious 45% ≥ university degree vs. 54% else	<u>44% disagreed</u> ProP: 42% vs. PNeo: 49% vs. PAX: 40% 44% females vs. 43% males 48% religious vs. 39% non-religious 48% ≥ university degree vs. 39% else	101 / 4 / 3
3.5 "There will probably be situations where I wish to follow my child's physician's advice because I lack the expertise to question their decision."	<u>91% agreed</u> ProP: 91% vs. PNeo: 89% vs. PAX: 93% 88% females vs. 95% males 95% religious vs. 84% non-religious 95% ≥ university degree vs. 82% else	<u>7% disagreed</u> ProP: 7% vs. PNeo: 9% vs. PAX: 3% 9% females vs. 3% males 3% religious vs. 11% non-religious 5% ≥ university degree vs. 10% else	105 / 2 / 3
<b>Main text: c) Emergencies</b> Written on questionnaire: Category 4: "Your perspective to treatments in emergencies"			Number of evaluable answers / cannot judge / missings
4.1 "I believe that in emergencies, treatment must start immediately. No time should be wasted on detailed information given."	<u>97% agreed</u> ProP: 98% vs. PNeo: 94% vs. PAX: 100% 97% females vs. 98% males 97% religious vs. 100% non-religious 100% ≥ university degree vs. 98% else	<u>2% disagreed</u> ProP: 2% vs. PNeo: 3% vs. PAX: 0% 2% females vs. 3% males 2% religious vs. 0% non-religious 0% ≥ university degree vs. 0% else	107 / 1 / 0
4.2 "Especially in emergencies, I rely on physicians to make the best decisions for me and my child."	<u>100% agreed</u> ProP: 100% vs. PNeo: 100% vs. PAX: 100% 100% females vs. 100% males 100% religious vs. 100% non-religious 100% ≥ university degree vs. 100% else	<u>0% disagreed</u> ProP: 0% vs. PNeo: 0% vs. PAX: 0% 0% females vs. 0% males 0% religious vs. 0% non-religious 0% ≥ university degree vs. 0% else	108 / 0 / 0

4.3 “I think, especially in emergencies, more research should be done to better prevent serious harm.”	<u>84% agreed</u> ProP: 81% vs. PNeo: 89% vs. PAX: 83% 84% females vs. 85% males 87% religious vs. 80% non-religious 81% ≥ university degree vs. 87% else	<u>3% disagreed</u> ProP: 5% vs. PNeo: 3% vs. PAX: 0% 3% females vs. 3% males 2% religious vs. 5% non-religious 3% ≥ university degree vs. 3% else	93 / 14 / 1
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<b>Main text: d) DC in the context of perinatal asphyxia</b>			Number of evaluable answers / cannot judge / missings
Written on questionnaire: Category 5: “Your perspective in the emergency of neonatal asphyxia, that your child will be harmed by oxygen deficiency during childbirth”. (this was described to parents at the beginning of the questionnaire)			
5.1 “I would be better able to cope better with the described emergency if I could be informed about it before labor/birth”.	<u>79% agreed</u> ProP: 84% vs. PNeo: 71% vs. PAX: 80% 77% females vs. 83% males 80% religious vs. 77% non-religious 81% ≥ university degree vs. 74% else	<u>19% disagreed</u> ProP: 14% vs. PNeo: 26% vs. PAX: 17% 19% females vs. 18% males 17% religious vs. 21% non-religious 18% ≥ university degree vs. 21% else	105 / 1 / 2
5.2 “I hope that in the emergency described, everything that is medically possible will be done for my child without my prior consent (to avoid sequelae and/or further damage)”.	<u>91% agreed</u> ProP: 91% vs. PNeo: 94% vs. PAX: 87% 88% females vs. 95% males 95% religious vs. 86% non-religious 87% ≥ university degree vs. 95% else	<u>5% disagreed</u> ProP: 5% vs. PNeo: 3% vs. PAX: 7% 6% females vs. 3% males 2% religious vs. 7% non-religious 3% ≥ university degree vs. 3% else	103 / 2 / 3
5.3 “If, after the emergency described, I was informed about the use of the study drug in my child without my prior consent, this would have a negative impact on my faith in my child's physicians”.	<u>26% agreed</u> ProP: 35% vs. PNeo: 17% vs. PAX: 23% 18% females vs. 40% males 18% religious vs. 36% non-religious 31% ≥ university degree vs. 15% else	<u>67% disagreed</u> ProP: 61% vs. PNeo: 74% vs. PAX: 67% 71% females vs. 60% males 73% religious vs. 57% non-religious 65% ≥ university degree vs. 72% else	98 / 3 / 7
5.4 “If my child had received the study medication, I would always suspect a side effect of the study medication if my child has health problems or long-term disabilities”.	<u>46% agreed</u> ProP: 44% vs. PNeo: 51% vs. PAX: 43% 40% females vs. 58% males 45% religious vs. 50% non-religious 50% ≥ university degree vs. 33% else	<u>43% disagreed</u> ProP: 47% vs. PNeo: 34% vs. PAX: 47% 49% females vs. 33% males 45% religious vs. 41% non-religious 39% ≥ university degree vs. 54% else	96 / 9 / 3
5.5 “I would also consider health problems to be side effects of the study drug, even if the physicians told me that these complications often occur after birth with oxygen-deficiency”.	<u>23% agreed</u> ProP: 19% vs. PNeo: 23% vs. PAX: 30% 24% females vs. 23% males 22% religious vs. 27% non-religious 18% ≥ university degree vs. 31% else	<u>69% disagreed</u> ProP: 74% vs. PNeo: 66% vs. PAX: 63% 69% females vs. 68% males 68% religious vs. 68% non-religious 74% ≥ university degree vs. 62% else	99 / 5 / 4
5.6 “It is important to me that independent physicians and ethics committees have examined this study and find it reasonable and ethically justifiable”.	<u>92% agreed</u> ProP: 95% vs. PNeo: 91% vs. PAX: 87% 88% females vs. 98% males 93% religious vs. 89% non-religious 97% ≥ university degree vs. 82% else	<u>4% disagreed</u> ProP: 5% vs. PNeo: 0% vs. PAX: 7% 6% females vs. 0% males 3% religious vs. 5% non-religious 8% ≥ university degree vs. 2% else	103 / 3 / 2

5.7 “It would reassure me to know that the study was recommended and developed by pediatricians, not by a pharmaceutical company”.	<u>94% agreed</u> ProP: 93% vs. PNeo: 91% vs. PAX: 97% 96% females vs. 90% males 93% religious vs. 93% non-religious 94% ≥ university degree vs. 92% else	<u>5% disagreed</u> ProP: 7% vs. PNeo: 6% vs. PAX: 0% 2% females vs. 10% males 5% religious vs. 5% non-religious 7% ≥ university degree vs. 3% else	105 / 0 / 3
5.8 “I think that I would make the right decision even in these emergencies. Therefore, I would prefer to only be informed in a few sentences and to be asked for short (oral) consent before administering the study medication.”	<u>55% agreed</u> ProP: 54% vs. PNeo: 60% vs. PAX: 50% 52% females vs. 60% males 48% religious vs. 64% non-religious 52% ≥ university degree vs. 56% else	<u>34% disagreed</u> ProP: 33% vs. PNeo: 29% vs. PAX: 43% 38% females vs. 28% males 38% religious vs. 30% non-religious 39% ≥ university degree vs. 28% else	96 / 10 / 2
5.9 “In the emergency described, I would be glad not to have been asked for permission to give the study medication, because I would have felt helpless and unable to make decisions, and I would probably have followed the advice of the physicians anyway.”	<u>43% agreed</u> ProP: 40% vs. PNeo: 34% vs. PAX: 57% 47% females vs. 35% males 42% religious vs. 43% non-religious 45% ≥ university degree vs. 39% else	<u>47% disagreed</u> ProP: 54% vs. PNeo: 54% vs. PAX: 30% 40% females vs. 60% males 48% religious vs. 48% non-religious 48% ≥ university degree vs. 46% else	97 / 9 / 2
5.10 “I think it is better to make a decision only in the acute emergency. I don't want to have to worry about such emergencies before giving birth.”	<u>17% agreed</u> ProP: 19% vs. PNeo: 20% vs. PAX: 10% 16% females vs. 18% males 17% religious vs. 18% non-religious 19% ≥ university degree vs. 13% else	<u>78% disagreed</u> ProP: 79% vs. PNeo: 71% vs. PAX: 83% 78% females vs. 78% males 78% religious vs. 75% non-religious 77% ≥ university degree vs. 77% else	102 / 4 / 2
5.11 “Information about the study via flyers, posters and newspaper articles are sufficient if more detailed information is provided later.”	<u>57% agreed</u> ProP: 51% vs. PNeo: 54% vs. PAX: 70% 62% females vs. 50% males 58% religious vs. 59% non-religious 53% ≥ university degree vs. 69% else	<u>36% disagreed</u> ProP: 47% vs. PNeo: 31% vs. PAX: 27% 29% females vs. 48% males 37% religious vs. 32% non-religious 40% ≥ university degree vs. 23% else	101 / 5 / 2
5.13 “For parents who don't want to participate, it's reasonable to develop an emergency card (similar to the organ donation card in some countries) that they can put into their pregnancy book and on which they can document their general rejection or approval of the study.”	<u>83% agreed</u> ProP: 86% vs. PNeo: 89% vs. PAX: 73% 87% females vs. 78% males 85% religious vs. 82% non-religious 87% ≥ university degree vs. 77% else	<u>8% disagreed</u> ProP: 12% vs. PNeo: 3% vs. PAX: 10% 6% females vs. 13% males 8% religious vs. 9% non-religious 8% ≥ university degree vs. 10% else	99 / 5 / 4

5.14 "I would actually use such an emergency card myself."	<u>41% agreed</u> ProP: 44% vs. PNeo: 34% vs. PAX: 43% 46% females vs. 33% males 37% religious vs. 50% non-religious 36% ≥ university degree vs. 54% else	<u>47% disagreed</u> ProP: 49% vs. PNeo: 51% vs. PAX: 40% 44% females vs. 53% males 53% religious vs. 36% non-religious 57% ≥ university degree vs. 26% else	94 / 8 / 6
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<b>Main text: d) DC in the context of perinatal asphyxia (ALBINO-Scenario)</b>			Number of evaluable answers / cannot judge / missings
Written on questionnaire: "Now imagine that your child has already received this medication and the treating physicians are asking you whether you would give consent for continued participation in the study."			
5.16 "If my child has been given study medication in an emergency without my prior consent, I would decide afterwards as follows (after detailed information):"	a. "I would agree to participate afterwards."	<u>48% agreed</u> ProP: 40% vs. PNeo: 43% vs. PAX: 67% 50% females vs. 45% males 50% religious vs. 46% non-religious 45% ≥ university degree vs. 56% else	101 / see answer d. / 7
	b. "I would refuse to participate afterwards."	<u>4% agreed</u> ProP: 7% vs. PNeo: 0% vs. PAX: 3% 3% females vs. 5% males 2% religious vs. 7% non-religious 5% ≥ university degree vs. 3% else	
	c. "I would have refused to participate before the birth."	<u>2% agreed</u> ProP: 2% vs. PNeo: 3% vs. PAX: 0% 2% females vs. 3% males 3% religious vs. 0% non-religious 3% ≥ university degree vs. 0% else	
	d. "I cannot judge"	<u>46% agreed</u> ProP: 51% vs. PNeo: 54% vs. PAX: 30% 46% females vs. 48% males 45% religious vs. 48% non-religious 47% ≥ university degree vs. 41% else	
5.17 "I think that giving a study medication without my prior consent is so inappropriate that I would take legal action against the physician investigators."	<u>8% agreed</u> ProP: 14% vs. PNeo: 0% vs. PAX: 10% 7% females vs. 10% males 5% religious vs. 14% non-religious 7% ≥ university degree vs. 8% else	<u>74% disagreed</u> ProP: 77% vs. PNeo: 74% vs. PAX: 70% 75% females vs. 73% males 75% religious vs. 71% non-religious 79% ≥ university degree vs. 69% else	89 / 10 / 9

<b>Main text: e) Pharmaceutical studies (in general)</b>			Number of evaluable answers / cannot judge / missings
Written on questionnaire: Category 6: "In the following questions, we would like to hear from you how you feel about drug studies in general."			
6.1 "I always prefer an appropriately tested treatment with a presumably safe but small therapeutic effect over an experimental treatment with a potentially greater therapeutic effect."	<u>40% agreed</u> ProP: 42% vs. PNeo: 40% vs. PAX: 37% 41% females vs. 38% males 37% religious vs. 48% non-religious 40% ≥ university degree vs. 44% else	<u>34% disagreed</u> ProP: 30% vs. PNeo: 40% vs. PAX: 33% 29% females vs. 43% males 35% religious vs. 30% non-religious 36% ≥ university degree vs. 28% else	80 / 22 / 6
6.2 "I disapprove of all drug studies."	<u>5% agreed</u> ProP: 7% vs. PNeo: 0% vs. PAX: 7% 6% females vs. 3% males 3% religious vs. 7% non-religious 7% ≥ university degree vs. 3% else	<u>92% disagreed</u> ProP: 93% vs. PNeo: 94% vs. PAX: 87% 88% females vs. 98% males 93% religious vs. 89% non-religious 94% ≥ university degree vs. 87% else	104 / 3 / 1
6.3 "I disapprove of all drug studies in children."	<u>18% agreed</u> ProP: 23% vs. PNeo: 9% vs. PAX: 20% 19% females vs. 15% males 20% religious vs. 14% non-religious 18% ≥ university degree vs. 13% else	<u>77% disagreed</u> ProP: 74% vs. PNeo: 86% vs. PAX: 70% 75% females vs. 80% males 77% religious vs. 77% non-religious 79% ≥ university degree vs. 77% else	102 / 4 / 2
6.4 "Studies are acceptable if there is a good chance of benefit and serious side effects are very rare."	<u>94% agreed</u> ProP: 93% vs. PNeo: 89% vs. PAX: 100% 93% females vs. 95% males 93% religious vs. 93% non-religious 95% ≥ university degree vs. 90% else	<u>3% disagreed</u> ProP: 2% vs. PNeo: 6% vs. PAX: 0% 3% females vs. 3% males 3% religious vs. 2% non-religious 2% ≥ university degree vs. 5% else	104 / 3 / 1
6.5 "If the study medication has previously been classified as "low risk for side effects" in other studies, I approve administration without my consent in an emergency."	<u>80% agreed</u> ProP: 72% vs. PNeo: 89% vs. PAX: 80% 81% females vs. 78% males 82% religious vs. 80% non-religious 82% ≥ university degree vs. 77% else	<u>17% disagreed</u> ProP: 26% vs. PNeo: 9% vs. PAX: 13% 13% females vs. 23% males 13% religious vs. 21% non-religious 18% ≥ university degree vs. 13% else	104 / 3 / 1

**Category 7: open-ended questions**

7.1 Please tell us what would make you allow your child to participate in research studies (including follow-up visits)?

7.2 If a study drug was administered to your baby as part of an emergency trial without informing you, please tell us what would be your reaction when you would be informed later and asked for consent for continued participation in that trial.

7.3 Do you have any recommendations for the investigators?

**Appendix II: Results of answers to all open-ended questions**

Open-ended questions	
7.1 Please tell us what would make you allow your child to participate in research studies (including follow-up visits)?	
ProP (n=39)	<ul style="list-style-type: none"> <li>• If there were the (smallest) possibility of a "cure" or improvement, I would take part in a study. The side effects shouldn't be too bad either. The child should not suffer from the medication.</li> <li>• That my child notices as little as possible, that the study is promising and has no further influence on the child's development.</li> <li>• Depends on the procedure, location, time required and above all what the child has to contribute, e.g. blood samples etc.</li> <li>• From pre-birth counseling.</li> <li>• Whether a disease exists.</li> <li>• Information about the study beforehand.</li> <li>• Whether risks and side effects are excluded or known. Presentation of the study, i.e. (as a mother), do I have the feeling that I know exactly what is being done, what is being observed, what the goals are, etc.</li> <li>• I must be convinced that it has more benefits (for my own and other children) than disadvantages.</li> <li>• What the risks are of continued participation or whether continued participation will lead to further improvement in health.</li> <li>• see 5.11.1</li> <li>• From danger to the child.</li> <li>• The safety of the drug, the procedure and the benefits of the study.</li> <li>• The benefits of the study for families who may later find themselves in a similar situation.</li> <li>• Trial stage of the drug.</li> <li>• It would have to be an "independent" unbiased scientific study, not only performed for economic reasons -&gt; recommended by my pediatrician -&gt; I would possibly get a second opinion; risk-benefit ratio" .</li> <li>• Prospects of success, side effects, possible alternatives.</li> <li>• I would probably let my child participate because I think research is extremely important. In a scenario where I have lost my trust in the doctors, I would probably find that very difficult.</li> <li>• Benefit to the child. Whether it restricts the child.</li> <li>• I wouldn't do it at all.</li> <li>• Is it the last option? What are the side effects? How many times already tested?</li> <li>• Trust in doctors, feeling of being sufficiently informed.</li> <li>• Trust, education and second opinion.</li> <li>• What is the disease, the chances of success and side effects.</li> <li>• Severity and number of side effects and the percentage chance of success.</li> <li>• From the drug, from the side effects, from the severity of the disease.</li> <li>• If there is no risk for my child, I would participate in such a study. At the follow-up, the question would not arise, since the drug has already been administered. So, I would participate!</li> <li>• Information and that I am convinced of the benefits of the study.</li> <li>• I need to be informed about the study and believe that the study is useful.</li> <li>• Difficult to answer. The information and the condition of the child.</li> <li>• From the prognosis without administration of the drug and from the risks and side effects of the drug.</li> <li>• It is important to have a basis of facts to decide this trade-off. What are the results so far?</li> <li>• Seriousness of the study. Seriousness and empathy of the physicians. Success of the treatment.</li> <li>• Very good chances of success, very few side effects -&gt; If the doctor has my trust and is fully convinced by the study.</li> <li>• Condition of child after birth; detailed information about study; helpful but usually probably not possible: an interview with parents of participating children.</li> <li>• The condition of the child.</li> <li>• Confidence in the study -&gt; Good/conclusive argumentation for sense and purpose -&gt; Believability of the treating physicians of the study.</li> <li>• This would be an option for me if there were no other alternatives that promised a positive cure.</li> <li>• Existing long-term studies, samples of patients &gt; 5000 without abnormalities.</li> <li>• It must not experience any side effects or problems from such a study and treatment.</li> </ul>

PNeo (n=23)	<ul style="list-style-type: none"> <li>• How much is already known about the drug.</li> <li>• From risk and benefit.</li> <li>• The extent and time required for follow-up examinations. The condition of my child after birth.</li> <li>• Effort, side effects, information.</li> <li>• Provided that the further treatments/examinations do not pose any additional risk, I would always participate in the study.</li> <li>• Whether I see a benefit in the study. Whereas I am generally more of a supporter of studies.</li> <li>• Preliminary conversation + info!</li> <li>• Own conviction of the drug and active ingredient.</li> <li>• From the success.</li> <li>• Information</li> <li>• That it is not the first study with this drug in children.</li> <li>• How well advised and cared for I feel by the doctors. Are the doctors concerned with the well-being of my child or just with participating in the study? My feeling would decide.</li> <li>• Study content, i.e., what does our child need to do? is he or she suffering? are there side effects from follow-up?</li> <li>• Previous studies, stochastic data, physician's vote.</li> <li>• Whether the follow-up would involve invasive methods and thus be harmful to my child. In general, however, I see the great general benefit of the study.</li> <li>• Depending on whether that is the "last chance" for my child.</li> <li>• It depends on the situation and on the medication or study.</li> <li>• The chances of success of the therapy.</li> <li>• If there is no other option.</li> <li>• From health condition.</li> <li>• From the explanation of possible risks, trust in the physicians, anticipated success of the therapy.</li> <li>• Follow-up examinations: time required, travel routes? Appointments are usually stressful situations for babies and young families. Can something be absorbed by a very child-friendly setting (local doctor instead of hospital? Childcare for older siblings? etc.). For participation in the study, my impression of the investigators will be decisive: Do they take me seriously? Do they inform me? Do they have time for me? Are they empathetic? Which idea of humanity and patients do they have?</li> <li>• Good information and trust in the treating physicians.</li> </ul>
PAX (n=25)	<ul style="list-style-type: none"> <li>• From whether I have the feeling that the doctors respond to me and take me seriously, and from whether I have the feeling that they know their stuff. On the ward, I sometimes had the feeling that the nurses knew better than the doctors how the children were doing, what they needed, how they were being treated.</li> <li>• Whether it is deemed necessary and only if it is in the best interest of my child (including subsequent examinations).</li> <li>• A transparent approach to the issue. Pros &amp; cons. And of course an important point: how extensive and time-consuming is it?</li> <li>• Aims of the study, side effects, risks and opportunities.</li> <li>• Kindness and understanding of the doctors and nurses. It depends on how stressful the investigations and examinations are for my child, whether the follow-up investigations are uncomfortable/painful and the frequencies.</li> <li>• I support studies in principle.</li> <li>• Above all, that the expected benefit for my child, as well as the common good, is greater than any harm to be feared (AND the study does not conflict with my religious certainties!).</li> <li>• It depends on whether the doctors have recommended this to me.</li> <li>• 1) Expected benefit for the child; 2) Potential risks to the child; 3) Benefit for the general public</li> <li>• Sufficient information about possible opportunities and risks.</li> <li>• Whether it contributes to the survival.</li> <li>• Detailed information about the benefits and opportunities of the drug and the importance of follow-up is important.</li> <li>• How few side effects the drug has and how well it works.</li> <li>• Would not let it participate if I am not convinced of it.</li> <li>• From the health condition of the child, the distance from home to the hospital, the side effects.</li> <li>• Prior informed consent and my consent for administration.</li> <li>• I would be advised on doctors (It is difficult) may also depend on the situation (no idea). Would have to discuss with my wife.</li> <li>• From the success of the study.</li> <li>• From faith: did the medication prevent worse in my child? 2. from the child: what is the condition and do I want to expect further hospital visits from him?</li> <li>• It depends on how important I recognize my child's participation in it and the benefit to my child and other children as well.</li> </ul>



<ul style="list-style-type: none"> <li>• From what his health condition is, if after the discharge from the hospital he has suffered consequential damages from the birth, I would continue to have him examined. However, if it is healthy at the core, I am not sure about it.</li> <li>• There is nothing to think about for me. If this situation were to occur, my child would have already received the medication anyway and then I would also participate in the study to help other parents.</li> <li>• From the physicians.</li> <li>• Previous information, side effects.</li> <li>• After weighing risks and opportunities. Data collection for the purpose of research is basically okay.</li> </ul>
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7.2 If a study drug was administered to your baby as part of an emergency trial without informing you, please tell us what would be your reaction when you would be informed later and asked for consent for continued participation in that trial.			
	Positive	Neutral	Negative
ProP (n=36)	<p>Positive thoughts: it's good that the doctors thought of the possibility; hopefully the drug will work for my child; what would it have been like without it?</p> <p>If the emergency really does call for immediate action without prior notice, I would be glad the doctors acted quickly, but as soon as there is time, I expect prior information.</p> <p>I would be glad that everything possible was done for my child.</p>	<p>First, I would like to have precise information about what the drug is and what side effects it has; What it can do for my child and what are the chances of success.</p> <p>Assuming prior information: would try to remain calm, thinking that by doing so you have done everything possible to help the child.</p> <p>Possibly confusion; good or bad depends on the situation.</p> <p>Depends on the effect.</p> <p>I cannot assess.</p> <p>Uncertainty at first, but if someone would explain to me what it's about, then it would be ok.</p> <p>Surprise, caution, need to get more information, skepticism.</p> <p>Uncertainty, which would be resolved if someone could show me that the medication is effective and is best for the child.</p> <p>Fear and hope, anger or gratitude depending on success of the drug.</p> <p>I would ask for precise information.</p> <p>First of all, I assume that the doctors will do everything possible to help my child. However, doubts may also arise that the child is above all a test subject. A stroke of luck for research.</p> <p>Provided the dosing was done under the assumption that there was a sufficiently high probability of no significant side effects, I would probably be grateful that everything was tried.</p> <p>In general, I trust the doctors that they will try everything possible to help my child in an emergency and weigh up the opportunities/risks to the best of their</p>	<p>I wouldn't like that it's still a study drug. A tested drug would be more ok! Especially in the case of study drugs, prior information would be particularly important to me!</p> <p>That would probably depend very much on the success of the treatment. A certain feeling of deceit would probably not be avoidable, even if it is irrational.</p> <p>Aggravation. After all, it is a drug that has not yet been approved.</p> <p>Insecurity, paternalism, distrust.</p> <p>I would definitely complain.</p> <p>Doctors ask why there was no brief explanation beforehand! There has to be so much time!</p> <p>Without prior clarification: panic, loss of trust</p> <p>If I hadn't received any information beforehand (i.e. during the pregnancy), I would have been irritated at first.</p> <p>Anger, fear, worry</p> <p>Anger, helplessness</p>

		<p>knowledge and current research. First, I would be surprised, but if the advantages outweighed, I would probably be glad to have gotten this chance.</p> <p>Shocked at first, after a brief explanation I would certainly understand.</p> <p>If everything goes well and my child gets better, I would be very grateful.</p> <p>Uncertainty; fear for the well-being of my child; My understanding and gratitude for trying to give my child the best possible treatment.</p> <p>How well tested is the drug? I would ask myself about the chances and risks.</p> <p>Concern for my child's health; great need for information.</p> <p>I would be grateful that the doctors did everything possible to help my child.</p> <p>Shocked at first, did this save the child from harm? --&gt; Relief; Mood is definitely dependent on how the child is doing.</p> <p>Worry about whether it might harm the child. Reassurance because everything has been done that is possible according to current research.</p> <p>Concern and the right to be informed in detail afterwards. side effects. What if the drug had not been administered.</p> <p>I'd probably be fine with that, if it successfully helped. In the event of complications, I cannot judge how I will react. In general, I have to trust the knowledge and actions of the doctors in such a situation.</p>	
PNeo (n=23)	<p>It's good that my child was given the best possible help. I am grateful because I know the consequential damage to be feared due to lack of oxygen.</p> <p>I suspect that averting the danger would relieve me so much that I wouldn't think too much about the application of the drug.</p> <p>I would think: The doctors did everything they could to help my child.</p> <p>Gratitude for trying everything possible to help my child.</p>	<p>I think it's the side effects that matter. If it was a success I would be happy. If there are any side effects, I would worry about what would have happened without the medication.</p> <p>Concern, but also the hope that the desired effect (and no consequential damage) will occur.</p> <p>There may be concern, but it depends on the child's condition.</p> <p>What side effects does the drug have? (Consequential damage).</p>	<p>I would have liked to have known in advance that my child could potentially participate in the study.</p> <p>I would lose confidence in the doctors and possibly take legal action against them.</p> <p>Disappointment, possibly anger because I wasn't asked in advance!</p> <p>Breach of trust.</p> <p>Shock</p>

	<p>I would be glad that action was taken.</p>	<p>If positive, I would be happy.</p> <p>Nothing at all.</p> <p>Uncertainty, personal discussion with the treating physicians is absolutely necessary.</p> <p>Concerns, but also hope.</p> <p>Mixed feelings: gratitude that my child was given the opportunity; Worry about side effects and late effects.</p> <p>Does that help or not?</p> <p>I would like to know why the drug was administered and what effects and side effects it has.</p> <p>I would like a full explanation and exact reasons why the doctors chose this drug and why they acted the way they did.</p> <p>Acceptance, the shock of the emergency would probably prevail.</p>	
PAX (n=25)	<p>I would be a bit worried because I would be afraid that the drug could harm my child. However, I would of course do everything to ensure that my child is healthy. If the doctors think it's the right decision to give the medication, then I can only trust that.</p> <p>I would hope that this would be as helpful to my child as possible, and even if not, that there would be a sense of progress that would help other children in a similar situation.</p> <p>If the application brings a positive result, then that would trigger joy. It's better to try something than to refrain from helping.</p> <p>Gratitude that everything is done for my child; fear of side effects; Hope for a normal life for my child.</p> <p>I basically trust the doctors to act to the best of their knowledge and belief. I would inform myself about the study drug to form an opinion.</p> <p>Relief was triggered in me; the hope that my child could do well is irreplaceable!</p> <p>I would be grateful if I knew that everything is being tried to save my child. I also expect that from a university hospital, which is why I go there and not to a birth center.</p>	<p>First, I would be irritated. However, if I look at the general situation after my two births, after the 1st spontaneous birth + the 2nd birth by caesarean section, I probably would not have been able to give my approval or rejection.</p> <p>If the doctors considered it necessary in this situation, I would probably (also out of trust in God) take note of the whole thing, but I would like to find out more about it.</p> <p>I wish for an open approach. Why was it necessary to give the drug? What risks does it entail? I desire openness and honesty of the medical team.</p> <p>I would first get clarification from the doctor. But basically, I would trust his expertise.</p> <p>If everything is ok, I wouldn't have any problems with it, since everything went well and my child survived the emergency.</p> <p>I would hope that there are no side effects.</p> <p>Initially surprised why no one informed about it. But this would give way to the relief that everything that seemed necessary was done for my child.</p> <p>I would decide that spontaneously.</p>	<p>I would be shocked! Extremely angry. Depending on the side effects my child would have afterwards. If the child were inconspicuous, I would probably just be shocked that something was done without permission.</p> <p>That would attack my confidence. I would then question everything and suspect several things about which I was not informed.</p> <p>Incomprehension, anger, doubts about legality; Would rate the approach as arrogant and high-handed.</p> <p>Speechless at first but glad that action has been taken. Stunned; Information from physicians.</p> <p>I would wonder why I wasn't informed beforehand.</p> <p>I would like some information before giving.</p> <p>Fright!</p>

	<p>Would everything be the same if my child had not received the medication and the birth had been normal? On the other hand, I would be grateful that the doctors would have reacted so quickly so that it wouldn't have gotten any worse.</p>	<p>I do not know.</p> <p>I would accept that.</p>	
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7.3 Do you have any recommendations for the investigators?	
ProP (n=24)	<ul style="list-style-type: none"> <li>• I think flyers are great! Also, to inform parents in advance about the consequences of a lack of oxygen --&gt; by flyer or in detail. Because the population is not sufficiently informed and educated about rare conditions or disabilities. Always talk plainly, it can be difficult at first, but it is the best solution. Do not beat around the bush.</li> <li>• Information brochures with the essential facts for expectant parents, as well as an emergency card on the maternity booklet are definitely helpful to avoid misunderstandings/conflicts</li> <li>• I think that all sounds very good. Expectant parents should be informed about the possibility, just as about toxoplasmosis or influenza, prevention or tests, etc. The idea with the emergency card in the maternity booklet should then be implemented.</li> <li>• You should provide information in advance in simple sentences. Also offer information evenings and flyers.</li> <li>• I would like to have the possibility to inform myself before the birth, so that I have at least heard something about such a study and that such a thing exists at all.</li> <li>• Hospitals that offer study participation should provide information about this in advance during registration, if possible. So the parents could decide in peace before the birth. Of course, only possible if the registration takes place a few days before delivery.</li> <li>• Informative talks as standard before a birth would still increase acceptance in my case.</li> <li>• I would inform the expectant mothers in detail before the birth. It should be known that there can be complications - for me it would be more reassuring to know all the treatment options beforehand.</li> <li>• Information about ALBINO already during pregnancy, possibly as part of the other information sessions with the gynecologist. Possibly additionally the "emergency card" with the options of consent &amp; refusal.</li> <li>• Ask the parents in advance. The idea with the emergency card in the maternity booklet is a good one.</li> <li>• I think in the clinics where the drug is used, it is important and helpful to try to inform the parents in advance.</li> <li>• In case of emergency, ask for consent anyway.</li> <li>• Research very much.</li> <li>• Side effects should be communicated clearly.</li> <li>• Do not conceal risks. Provide honest information.</li> <li>• Detailed information during the prenatal check-up, at the gynecologist's office.</li> <li>• Expectant parents should be informed in detail about the ALBINO trial already during pregnancy.</li> <li>• Good arguments, more positive successes, to have an explanation for everything at least.</li> <li>• Transparency; publication of previous results create trust.</li> <li>• The widest possible range of information even before birth (flyers and posters are not enough). Extreme care in the study. Maximum independence from interest groups.</li> <li>• Better information: what are the consequences without medication; what are the consequences with medication; statistics; what exactly does the medication do? I would have liked more information about the drug in the questionnaire (I will now inform myself on the Internet).</li> <li>• To do a lot of advertising, in every possible way, so that expectant parents can deal with the topic before birth and actually clarify initial questions about "What does oxygen deficiency at birth mean" in advance. Then decisions in emergencies may be easier.</li> <li>• Basic information before birth about the gynecologist, if everything is still okay, then I know the medication and the procedure and can form an opinion beforehand.</li> <li>• It is important that new helping medications are developed and tested. But for new parents it is very scary, because nobody wants to use their child as a "laboratory rabbit".</li> </ul>
PNeo (n=12)	<ul style="list-style-type: none"> <li>• Test the side effect in advance. No influence of companies in the study. Test the drug in children only when the risks of administration are clear.</li> <li>• You should clearly contrast the consequences that may occur if the drug is not given (brain damage...) with the risks of giving it (drug vs. no drug).</li> <li>• Prior clarification of the parents.</li> <li>• Continue!!!!</li> <li>• A short explanation with the most important things is enough.</li> </ul>

	<ul style="list-style-type: none"> <li>• Do not get discouraged.</li> <li>• Difficult topic. Unfortunately, no advice ready, except to enlighten the parents very gently afterwards.</li> <li>• Provide information about this option in advance.</li> <li>• Enlighten; do not act in the interests of the pharmaceuticals.</li> <li>• If the doctors are convinced of this drug and this certainty becomes clear in the discussion, parents can more easily decide to allow administration of study drugs.</li> <li>• Enlightenment should be given in a way that is appropriate and in simple language and, absolutely, in the language of the parents. Not when the birth has already begun, but during a preventive consultation, e.g. with a midwife.</li> <li>• Don't be "Mr./Mrs. Doctor anyway", be aware that the parents' world has probably collapsed. Empathy should take precedence over expertise and skills.</li> </ul>
PAX (n=20)	<ul style="list-style-type: none"> <li>• Be very careful with the parents, an emergency birth (as in our case) is a "borderline situation" in which parents also lose their calm quickly. Such "unsafe" administration of medication may cause additional anxiety.</li> <li>• I wish the physicians that they always have the human being in the foreground and that they are not only guided by the study itself in their actions.</li> <li>• Humanity comes first, followed by honesty, openness, respect and professional competence. Don't make us feel like a lab animal! Child-friendliness must be a prerequisite.</li> <li>• I recommend not only to the doctors but to all who are working on this study: "Imagine you are doing this for your own child." Only then you can do it right.</li> <li>• God's blessing!</li> <li>• You should continue to strengthen couples who are uncertain and give them hope by telling them about your successes so far.</li> <li>• Implement verbal consent in emergencies. Do not implement the emergency card. Assessment based on experienced situation with oxygen deficiency at birth of our child.</li> <li>• Provide good and comprehensive information and transparency.</li> <li>• Make expectant parents aware in advance through the gynecologists.</li> <li>• If possible, I would like to receive information about the study and the planned administration of the drug in the case of an emergency before birth.</li> <li>• Keep the essentials in mind! Is it really always necessary to give this drug? I wish you good luck and that your medicine helps the children as you hope!</li> <li>• Always keep looking for new methods.</li> <li>• I have never heard about this study. Therefore, I recommend to inform all expectant parents about it. I think that way you get the most approvals and the parents don't have to doubt etc.</li> <li>• Keep going. I have my fingers crossed that the ALBINO trial will be successful and help many babies.</li> <li>• Inform the parents beforehand! "If this and that were to happen, we would act immediately and do this and that; Would that be ok for you!?" Then parents are already prepared! And don't feel left out! And can have a say if they have been informed beforehand.</li> <li>• The study drugs, which will be administered in an emergency, should be addressed or discussed in advance."</li> <li>• To do as much preliminary work as possible (as described) with flyers and posters, so that it only has to be clarified afterwards in rare cases!</li> <li>• As long as you act on behalf of the child, I wouldn't worry too much about the parents. The life and health of the child always come first.</li> <li>• It's difficult to find a way. On the one hand, it is good to be informed beforehand about possible treatments. On the other hand, as a pregnant woman, you don't want to deal with such situations, as it can drive you extremely crazy... I wish the doctors a lot of strength to find the best way for everyone and good luck with the study.</li> <li>• Please take part in the study, it is always important. Thank you to the doctors who helped my child. Thank you, Dresden.</li> </ul>