



PHASE 2/3/4 INFORMED CONSENT PEDIATRIC STUDIES

Page: Instructions

How to use this template:

The template includes information in different colors and fonts, to help easily identify

- general guidance and instructions
- places where information should be inserted
- standard text

Following are the typographic conventions in the template:

Type of text	How to use
Blue Text	<p>General guidance and instructions.</p> <p>Use as directions or advice to help develop the appropriate content for the informed consent form.</p> <p>NOTE: These directions should be deleted from the final consent document.</p>
<Italics text in carets>	<p>Places to insert information.</p> <p>Enter one of the choices when given or appropriate free text information for the study.</p> <p>NOTE: All italicized text in carets should be deleted from the final document.</p>
Red text	<p>Mandatory text – The text must be used in its entirety. Any changes to this text must be approved by the appropriate group (e.g., Legal, Pharmacogenomics).</p> <p>For text indicated for a country or region, select the appropriate text (e.g., country specific compensation language).</p> <p>NOTE: All appropriate mandatory text should be converted to black text in the final document.</p>
Standard text	Suggested wording. Text may be modified.

Headers


The header on each page of the consent form must include the page number and total number of pages, the date of the draft, final, revision document, and the protocol identifier.

Footers

The footer on each page of the consent form may include spaces for the parent or legally-acceptable representative to date and initial.

Final printing

Remove this instruction page, as well as, all general instruction text in blue and instructions to insert text in carets from the final consent fo

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ICD	Protocol ID: A8841004		Date (created/updated): 10 March 2008	
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Title of Study: A PHASE 1, OPEN LABEL, SINGLE DOSE STUDY TO INVESTIGATE THE PHARMACOKINETICS, SAFETY AND TOLERABILITY OF DALBAVANCIN IN HOSPITALIZED ADOLESCENTS, AGED 12 THROUGH 17 YEARS RECEIVING STANDARD INTRAVENOUS ANTI-INFECTIVE TREATMENT FOR BACTERIAL INFECTIONS

Study Number: A8841004

Hospital or
Institution

Subject Name

1. NATURE AND PURPOSE OF STUDY

This form is called an informed consent form. It contains a full explanation of the study that your child is being invited to take part in and a consent form that you will be asked to sign if you and your child decide to take part. Your child is being asked to take part in a research drug study run by Pfizer because he or she has an infection. Your child will be evaluated for the study only after you agree to consent to their participation by signing this form. If your child qualifies for this study, he or she will be asked to complete all the study procedures described below.

This study is being done to find out the good and bad effects of a drug that is not approved for sale to treat infections in children (those less than 18 years of age). This study includes teenagers, defined as age 12 through 17 years old. The drug is called dalbavancin and is only available as an intravenous medicine (intravenous means the drug is given in the vein). Dalbavancin has been given to about 1282 people and there is evidence the drug works, although it has not yet been approved to be marketed for the treatment of skin and soft tissue infections caused by Gram-positive bacteria in adults. This drug has not been studied in children and is not approved for use in children. Because the drug has not been studied in children, the purpose of this study is to evaluate whether the level of drug in the blood in children will reach a level that will be effective in treating infections as well as to evaluate safety of the study drug. This study drug, dalbavancin, will not be used to treat your child's infection but your child will receive another antibiotic to treat their infection in order to be a participant in this study.

Because this is a research study, dalbavancin will be given to your child only during this study and not after the study is over.


2. EXPLANATION OF PROCEDURES TO BE FOLLOWED

A. PROCEDURES OR THERAPY

This study will be done in hospitalized adolescent children; however, if your child is discharged from the hospital you and your child agree to return here for appointments. The following is an explanation of the tests and procedures that will be done during your child's participation in the study:

Screening visit:

If you consent to allow your child to participate, your study doctor will evaluate whether your child is appropriate for the study. The doctor will perform a physical examination, which will include checking a

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blood pressure and heart rate. In addition, your child will have an electrocardiogram (a test of heart activity). In addition, urine and blood samples (1 and one-half a teaspoon of blood) will be collected for routine laboratory testing.

If your child is female and is of age, she will be asked to give a urine sample for pregnancy testing.

Throughout the study, your child will have several blood samples collected. Most of these blood samples will be used to determine the amount of dalbavancin in the blood. A half-teaspoonful of blood will be collected each time.

Study Days 1 - 7:

If the result of the examination done at the screening visit indicates your child is appropriate to participate in the study, the study doctor may repeat the physical exam before giving the study drug on day 1. Your child's blood pressure, heart rate, electrocardiogram and medical history (if changed since the screening visit) will be taken. Seven (7) blood samples (one-half teaspoonful each) will be collected at different time points over the first 24 hours to measure the amount of dalbavancin in the blood. A blood sample for safety laboratory testing (1 and one-half a teaspoon of blood) will be repeated if it has been more than 72 hours since the collection of the sample taken at the screening visit. If your child is female and is of childbearing age, she will be asked to give a urine sample for pregnancy testing only if the test done at the screening visit was more than 24 hours old. In addition, the collection of urine for 24 hours will begin at the time the study drug is started and continue through day 2.

Following the exam and testing, your child will receive the study drug, dalbavancin, through the vein for the first day of the study. The drug will take approximately 30 minutes to receive the full dose through the vein. The doctor will evaluate your child for any side effects to the study drug during and after the drug is given. This will help us determine the safety of the study drug.

After your child receives the study drug an electrocardiogram, heart rate and blood pressure will be taken to check for any changes that may be from the drug. Your child's blood pressure and heart rate will be checked again at 4 and 12 hours from the time the study drug was started.

On days 3 and 7 one blood draw (half a teaspoon) per day will be taken to measure the amount of dalbavancin in the blood.


On day 7, a physical examination will be performed and your child's blood pressure and heart rate will be measured. Blood samples will be collected (1 and one-half a teaspoon of blood) for routine laboratory testing.

Study Day 14:

On day 14 of the study one blood draw (half a teaspoon) will be taken to measure the amount of dalbavancin in the blood.

Study Day 21:

On day 21 of the study one blood draw (half a teaspoon) will be taken to measure the amount of dalbavancin in the blood.

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Study Days 28 and 56:

On days 28 and 56 of the study a physical examination, blood pressure, heart rate, and electrocardiogram will be performed on your child. Blood samples (2 teaspoonsful of blood) will be collected for routine laboratory testing and to measure the amount of dalbavancin (study drug) present in the blood. If your child is female and is of age, she will be asked to give a urine sample for pregnancy testing.

The study doctor will discuss the good points and bad points of the study to help you decide if your child's participation in this study will be of benefit.

WHAT ARE THE COSTS?

Pfizer will cover the cost of all examinations, tests, treatment, and procedures listed in this consent document. You may need to receive medical care that is not listed in this document. Pfizer will not cover the costs of that care unless it is needed to treat a research injury (see the discussion of research injury, below).

B. EXPECTED DURATION OF THE STUDY AND NUMBER OF SUBJECTS EXPECTED TO PARTICIPATE

There will be about 12 people in this study. Your child will be in the study for about a maximum of 63 days. This study is also being run at about 6 other sites.

If you allow your child to take part in this study, you and your child agree to return here for appointments. The doctor will assess your child's response to the study drug during the scheduled appointments.

C. STUDY RESTRICTIONS/SUBJECT RESPONSIBILITIES


Tell a study doctor immediately if your child has:

- A side effect
- An injury
- Any symptom or complaint

Please call _____ at _____.

Provide 24-hour contact information (including phone numbers and names if possible). Additional information should be provided to the subject regarding whom to contact in the event of a research-related injury.

Inform your study doctor or nurse if your child has been started on any new medications or received any treatments during the trial.

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If your child is discharged from the hospital, you should bring your child to all scheduled study visits and follow the instructions provided by the study doctor or nurse.

3. POSSIBLE SIDE EFFECTS, RISKS, AND DISCOMFORTS

As with all research studies, the drug treatment may involve risks that are already known as well as risks that are currently unknown including an allergic reaction to the drug (your child's body has a reaction to the study medication). Therefore, it is important that you report **all** symptoms and side effects that your child experiences as soon as they occur, whether or not you think they are caused by the study drug. In addition, your child's symptoms may not be controlled by the study drug or may even worsen.

A. SIDE EFFECTS

In the past, studies using dalbavancin have been done in both animals and approximately 1282 adult humans using either one single dose or several doses once a day for up to 7 days. The results of the studies showed the most common side effects, thought to be related to dalbavancin, included diarrhea, heartburn, nausea, abdominal pain, constipation, anemia, loss of appetite, headache, mild fever, skin flushing, pain and redness of the skin at the area where the drug was given in the vein. The side effects were reported as mild or moderate in severity. Blood pressure, heart rate, physical exams, laboratory measurements and electrocardiograms (ECGs) were normal or slightly abnormal. The most common abnormal blood test results that occurred in approximately 1.4% of patients were liver function test (blood test measuring liver health) abnormalities. The liver function tests were found to be normal about one week after receiving their last dose of dalbavancin. Approximately 3.5% of people had side effects that led to discontinuation of dalbavancin with the most common reported as rash and itching.

During the study, your child will be closely monitored for previously reported and unreported (new) side effects. If your child experiences significant side effects, or has any test that becomes significantly abnormal, dalbavancin may be stopped immediately. Throughout the study you will be told of any changes in the way the study is done and any new risks or side effects.


B. CHILDBEARING POTENTIAL

FEMALES

There could be risks to an unborn child in this study. If your child is pregnant or becomes pregnant during the study, these risks could affect your child or the unborn child. Females will agree to use birth control during the study. Your female child must continue using birth control for 1 month after the study is over. The study doctor must approve the form of birth control.

Before the study, a pregnancy test is done for all females. This test might not detect an early pregnancy. Pregnancy tests may be repeated during the study. If you think your child is pregnant, tell the study doctor immediately.

Pregnancy will be a reason to stop study treatment. If your child becomes pregnant during the study, she may be discontinued from study participation for safety reasons. If your child becomes pregnant within 28 days after she has stopped taking study drug, we ask that you contact your study doctor for safety monitoring. In either case, please make your obstetrician aware of your child's study participation. Your study doctor will ask that your child, or your obstetrician, provide updates on the progress of your child's

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pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

MALES

If your child's partner thinks she is pregnant during the study or within 28 days after your child has stopped taking study drug, tell your study doctor immediately. If your child's partner becomes pregnant, she will be asked to sign a release of information form to allow your study doctor to contact her obstetrician to collect updates on the progress of the pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

C. DISCOMFORTS

Some known discomforts that your child may experience from the blood drawing procedure are pain, burning, or the development of a bruise, at the site where the needle is placed to draw the blood. All blood samples for the study may be collected from catheters (tubes) that are placed inside a vein or with a needle stick. Catheters may be left in place for the duration of your child's stay in the hospital for the collection of blood samples. If a needle stick is needed to collect the blood sample, medicine can be applied to the skin to numb the surface before the needle stick.

4. COMPENSATION

If your child experiences a research injury, *<investigator or institution name>* will provide or arrange for medical treatment at no cost to you or your child. Pfizer will cover the costs of this treatment. A research injury is any physical injury or illness caused by your child's participation in the study. If your child is injured by a medical treatment or procedure that he or she would have received even if he or she weren't in the study that is not a research injury. Payment for such things as lost wages, expenses other than medical care, or pain and suffering is not available. To help avoid injury, it is very important to follow all study directions. You and your child are not giving up any of your legal rights by signing this form.


5. POSSIBLE BENEFITS OF THE STUDY

Benefits

Your child will get study drug at no cost to you. There are no medical benefits for your child from this study. **Information from this study may benefit other children with infections in the future.**

Payment to Subjects

If your child is discharged from the hospital he/she is expected to return to here for study appointments. Meals, parking, and ground transportation relating to the participation of this trial will be reimbursed in the amount of \$XXX.XX for each appointment.

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6. INVESTIGATOR COMPENSATION

The investigator (study doctor) or his/her institution is being compensated by the study sponsor for his/her participation in this study.

7. REMOVAL FROM THE STUDY

Your study doctor or Pfizer Inc may decide to take your child out of the study if:

- a. You and your child do not follow the directions of the study doctor
- b. Your child develops a serious illness that is not related to taking part in the study
- c. Your study doctor decides that the study is not in your child's best interest
- d. Pfizer or the FDA (Food and Drug Administration), or Institutional Review Board/Independent Ethics Committee (IRB/IEC) decides to stop the study
- e. Your child becomes pregnant, intends to become pregnant or is nursing a child during this study.

If your child is taken out of the study, he or she may undergo some tests. These tests may include:

- Physical exam
- Blood work and urine test
- Pregnancy test for females of childbearing potential


The tests are to protect your child's safety. Your study doctor may also recommend other treatments.

8. RIGHT TO WITHDRAW FROM THIS STUDY

Taking part in this study is up to you and/or your child if they are required to sign and assent form. You and/or your child may choose not to take part in this study or may decide to leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty. Your child will not lose any benefits to which he or she is otherwise entitled. Your decision will not affect your child's access to medical care in the future. Upon withdrawal from the study, samples already taken will be analyzed as planned unless you state that you will not allow this at the time of leaving the study.

If you decide to leave the study, your child will undergo some tests. These tests include:

- Physical exam
- Blood work and urine test
- Pregnancy test for females of childbearing potential

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The tests are to protect your child's safety.

9. CONFIDENTIALITY

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your child's health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify your child.

If you sign this informed consent form, you are giving permission for the use and disclosure of your child's health information for purposes of this research study. You do not have to give this permission. However, if you do not, your child will not be able to participate in the study.

Who Will Use and Disclose My Child's Health Information?

The investigator and his or her research staff (the Study Team) at [Name of Covered Entity] may use your child's health information to conduct, review, and determine the results of the study. The Study Team may also use your child's information to prepare reports or publications about the study. **However, your child's name will not appear in any report or publication.** The Study Team may disclose your child's information to others, as discussed below.

What Health Information will be Used and Disclosed?


The Study Team will record your child's medical history, the treatment he or she receives, and the results of examinations and tests done during the study on study forms. Your child's name will not appear on the study forms. Instead, your child will be assigned a subject identification number. The Study Team will send the completed study forms to the study sponsor. This type of information may also be shared with others, as described below.

Your child's medical records may include other health information about him or her and may include documents that directly identify him or her. Representatives from the groups identified below may need to look at your child's medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

Who Will Receive My Child's Health Information?

Your child's study information may be shared with the following people or groups:

- The study sponsor (Pfizer Inc) or its representatives, including companies it hires to provide study-related services
- Researchers who are conducting this study at other study centers
- The institutional review board (ethics committee) that approved this study and any other committees responsible for overseeing the research
- Government health agencies (such as the Food and Drug Administration) in the US or other countries
- [Insert additional people or entities, as appropriate]

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Representatives from these groups may receive information from your child's study forms or may review your child's medical records (as described above) or both.

Will My Child's Information be Protected by the Privacy Rule After it is Disclosed to Others?

[Name of Covered Entity] is required by the Privacy Rule to protect your child's health information. After your child's information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your child's information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your child's information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about drugs or diseases or to help design better studies in the future. When using your child's information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services. This could result in transfer of your child's information outside the United States. However, your child's name will never appear in any sponsor reports or publications, or in any future disclosures by the sponsor.

What Happens if My Child Leaves the Study Early?

If your child stops participating in the study early for any reason, the Study Team will tell the sponsor why. If the Study Team asks you to bring your child to any more study visits and you agree, the Study Team will send the sponsor information from those visits as well. All information collected about your child may continue to be used and disclosed.

Will My Authorization Ever Expire?

This Authorization does not have an expiration date. The Study Team may need to correct or provide missing information about your child even after his or her study participation is over. The review of your child's medical records (described above) may also take place after the study is over.


May I Take Back My Authorization?

You have the right to take back (revoke) your Authorization at any time by writing to [name and address]

If you revoke your Authorization, the Study Team will not collect any new health information about your child. However, they can continue to use and disclose any already collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, your child can no longer continue to participate in the study.

May I Look At My Child's Study Information?

You have a right to see and make copies of your child's medical records. However, to ensure the reliability of the study, you will need to wait to see your child's study records until the study is completed.

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10. OFFER TO ANSWER QUESTIONS ABOUT THIS STUDY

Before you sign this form, you should ask questions about anything that you do not understand. The study staff will answer questions before, during, and after the study.

If you or your child have questions about this study or how it is being run, you should contact:

Please call _____ at _____.

Provide (1) site contact: study physician's name, coordinator's name; (2) site telephone number; (3) site address.

If you or your child have questions about your child's rights in the study, you should contact:

Where required provide name, phone number and address of any of the following: (1) Institutional Review Board/Independent Ethics Committee (IRB/IEC); (2) Patient rights advocate; (3) Institutional contact; and/or, (4) Bioethicist.


If you or your child have questions about side effects, you should contact: (Provide (1) site contact: study physician's name, coordinator's name; (2) site telephone number)

24 hour phone number: Please call _____ at _____.

11. CONSENT

- You have read (or someone read to you) this Informed Consent Document.
 - This document describes the purpose and nature of this study.
- You have had time to review this information.
- You have been offered a chance to ask questions.
- You got answers to your questions that you are satisfied with.
- If your child does not take part in the study your child will not lose any benefits.
- If your child leaves the study your child will not lose any benefits.
- If your child leaves the study you and your child will not lose any legal rights.
- Your child's participation in this study is completely voluntary.

You will get a copy of this signed Informed Consent Document for your records.


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You agree that your child may participate in this study.

It is your responsibility to tell the study doctor about all changes in your child's physical or mental health during the study.

For US only: (Where required - You will also get a copy of the Experimental Subject's Bill of Rights.)

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CONSENT TO PARTICIPATE IN THIS STUDY

I have read, or have had read to me, in language understandable to me, the above information. The content and meaning of this information has been fully explained to me.

I have had time and opportunity to ask any questions that I have about the study and this form, and all my questions have been answered. I have read all pages of this consent form and the risks described. I voluntarily give consent for my child to take part in this study. By signing this consent form, I certify that all information I have given, including my child's medical history, is true and correct to the best of my knowledge.

I understand that I will receive a copy of this signed consent form.

Printed name of subject

Signature of subject:

Date

Please date your own signature at the time of signing.

Printed name of legally acceptable representative

Signature of legally acceptable representative

Date


(Signature of an impartial witness is required if the subject or subject's legally acceptable representative cannot read.)

Printed name of impartial witness

Signature of impartial witness

Date

☐ Not applicable

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(The investigator, or person designated by the investigator to conduct the informed consent process, must sign and date form at the same time as the subject.)

Printed name of person explaining consent

Signature of person explaining consent

Date

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