WHAT HAPPENED DURING THE STUDY?
Over a three-month time period, a total of 142 blood samples were taken from 73 newborns (about 2 samples per newborn). These samples were taken as part of the newborns’ regular medical care, so only a few extra needle sticks were needed.

WHAT WERE THE STUDY RESULTS?
Most of the infants responded best to a dose that was based on:
• Their weight
• Their age
• How far along in the pregnancy their mothers were when they were born

Based on these findings, researchers were able to suggest a dose of ampicillin that was both safe and effective for newborns.

WHAT SIDE EFFECTS DID NEWBORNS HAVE?
None of the newborns had any side effects from taking the medicine.

WHAT HAPPENS NEXT?
The results of this study were sent to the U.S. Food and Drug Administration (FDA), a government agency that approves drugs and devices used to treat patients. Our findings were used to change this medicine’s “label,” or the printed information that is included along with the drug. The findings are also published in scientific journals. Both the label and publications can provide doctors with information to help them give the safest, most effective dose of this medicine to children.

WHERE CAN I LEARN MORE ABOUT THIS CLINICAL TRIAL?
A summary of the results can be found online at pediatrictrials.org. If you have additional questions, please speak with the doctor or staff at your study site.

* This summary was completed on June/2020. Newer information since this summary was written may now exist. This summary includes only results from one single study. Other studies may find different results.