

 Yourway Transport 6681 Snowdrift Road Allentown, PA 18106		Operations: 610-395-9198 Main 610-391-9002 Fax 610-509-9722 Mobile		Waybill/Job# <b>376337</b>			
Bill Shipper Account# <b>30216</b>				Shipper's Reference <b>IKA 7001, #010620</b>			
<b>Shipper</b> P/U Agent      Date      Time				<b>Consignee</b>			
Sharp Clinical Services 1041 W Bridge Street  Phoenixville, PA 19460 USA  Dawn Zeccardi 484-844-2243				Jaime Gomez 3075 E. Floradora  Fresno, CA 93703 USA  559-761-3005			
Contents: <b>Pharmaceuticals</b>		Declared Value		Special Handling:			
		Customs Value <b>USD</b>					
Pieces: <b>2</b>		Weight: <b>78</b>		Dimensions - <b>24 x 18 x 12</b>		Print Consignee's Name <b>JAIME GOMEZ</b>	
						Date <b>11-22-13</b>	
In Compliance with Part 109 please complete security endorsement I certify that this shipment does not contain any unauthorized explosive or destructive devices or hazardous material. I consent to a search of this shipment. I am aware that this endorsement and original signature along with other shipping documents will be retained on file until the shipment is delivered. Shipper agrees to inspection and screening of cargo.				Consignee's Signature 		Time <b>10:20 AM</b>	
Shipper's Signature 		Print Shipper's Name Dawn Zeccardi		Date/Time 28 Oct 2013		Unless a greater value is declared, the shipper agrees that the value of the property is released to an amount not exceeding \$50.00 for any shipment of 100lbs or less, and not exceeding 50 cents per pound for shipments weighing in excess of 100lbs.	
First ID Type Photo Y N ID Expired Y N ID Number		Second ID Type Photo Y N ID Expired Y N ID Number		Agent check here if inspected <input type="checkbox"/>			
Job Type / Service Level <b>Air Overnight</b>							



**YOURWAY TRANSPORT DELIVERY ACCOUNTABILITY FORM**  
**IKARIA PROTOCOL: IK-7001-PAH-201**

<b>Site Number, Study Coordinator &amp; Phone Number</b> <b>Site #: 01050, Study Coordinator: Rebekah Garcia Phone: 559-459-6399</b>	
<b>Subject ID</b> 01050001	<b>Arrival Time (24 Hr Clock)</b> <div style="border: 1px solid black; padding: 2px; display: inline-block;">09:40</div> <b>Departure Time (24 Hr Clock)</b> <div style="border: 1px solid black; padding: 2px; display: inline-block;">10:20</div>
<b>Date of Visit</b> <div style="display: flex; justify-content: center; gap: 5px;"> <div style="border: 1px solid black; padding: 2px;">22</div> <div style="border: 1px solid black; padding: 2px;">NOV</div> <div style="border: 1px solid black; padding: 2px;">2013</div> </div> <div style="display: flex; justify-content: center; gap: 20px; font-size: small; margin-top: 5px;"> <span>DD</span> <span>MMM</span> <span>YYYY</span> </div>	

**Driver information**

**THE IxRS BLINDED SUBJECT CONSIGNMENT AND STOCK REPORT WILL BE NEEDED FOR EVERY DELIVERY / RETURN.**

N/A For Initial Patient Shipment (Day 0, Week 1) Confirm That Shipment Contains Minicylinders, Locking Cabinet with Keys, magnetic key holder & HHCP clipboard.

For all shipments after Week 1, confirm that Minicylinders are delivered and used minicylinder kits are picked up.

For all minicylinder returns:

- ✓ Ensure that all minicylinders in each kit have the same kit number.
- ✓ Used kits will have a broken tamper evident seal.
- ✓ Used minicylinders should have the black cap and valve shrink cap removed.
- ✓ Check off the minicylinder serial numbers being returned on the **BLINDED SUBJECT CONSIGNMENT AND STOCK REPORT.**

For any missing minicylinders, please make reasonable effort to locate them and return them to the appropriate kit.

For all visits: Perform accountability below for any shipments containing device or minicylinders.

**Drug Accountability - Delivery of Minicylinders: (What is delivered to the subject home)**

Date kit received	Shipment/ Consignment #	Kit #	Is the kit received intact and sealed? If yes, mark "Yes". If no, please comment.
22 NOV 13	Job 376337 / 010620	28160	Yes
22 NOV 13	Job 376337 / 010620	28246	Yes
22 NOV 13	Job 376337 / 010620	28726	Yes
22 NOV 13	Job 376337 / 010620	28842	Yes
22 NOV 13	Job 376337 / 010620	29233	Yes
22 NOV 13	Job 376337 / 010620	29395	Yes



**YOURWAY TRANSPORT DELIVERY ACCOUNTABILITY FORM**

**IKARIA PROTOCOL: IK-7001-PAH-201**

**Drug Accountability – Return of Minicylinders (What are you taking from the subject’s home):**

Kit #	Number of Minicylinders in each kit	Please note any deficient or missing Minicylinders Below (please list how many are missing, serial #'s and/or any comments)**:
31464	8	
31675	8	
31965	8	
32109	8	
33998	8	
34199	8	
34284	8	

\*\* If minicylinders are missing, please make reasonable effort to locate them.

\*\*If any drug product is being returned with a deficiency, "deficiency" should be written next to corresponding kit.

**Device Accountability – INO Pulse Device (in the subject home)**

Total # of DEVICES DELIVERED: <u>          N/A          </u>	
<u>          Device serial #          </u>	<u>          Shipment/Consignment #          </u>
N/A	N/A
N/A	N/A
Total # of DEVICES RETURNED: <u>          N/A          </u>	
<u>          Device serial #          </u>	<u>          Reason for device return (deficiency, routine maintenance)          </u>
N/A	N/A
N/A	N/A
N/A	N/A

**Driver Signature:** \_\_\_\_\_ *Joseph Laubs*

**Date:** \_\_\_\_\_ *22 Nov 13*

**During the visit, did the subject volunteer drug/device related deficiencies/complaints?**

No  Yes

If yes, please confirm that subject was instructed to call their study site to report?  No  Yes

NOTE: Do NOT actively seek this information

**IF FOR ANY REASON THE PATIENT HAS A DEFICIENCY TO REPORT OR QUESTION, PLEASE CONTACT THE CLINICAL SITE IMMEDIATELY & HAVE THEM SPEAK WITH THE STUDY COORDINATOR.**

**IN THE EVENT OF AN EMERGENCY, PLEASE CONTACT THE CLINICAL SITE DIRECTLY OR HOME HEALTH PROVIDER AT +1-877-516-7703**



# IKARIA IK-7001-PAH-201

## Blinded Subject Consignment and Stock Report

This report was generated on 24 Oct 2013 08:05:28 (UTC Date/Time)

**Site:** 01050  
**Investigator Name:** Vijay Balasubramanian  
**Subject number:** 01050001  
**Randomization Number:** 10288  
**Consignment Number:** 010620  
**Devices to be dispatched:** N/A

Minicylinders to be dispatched:	Kit Number	Serial Number
	28160	HM0019620 ✓
	28160	HM0019602 ✓
	28160	HM0019628 ✓
	28160	HM0021306 ✓
	28160	HM0019642 ✓
	28160	HM0021314 ✓
	28160	HM0019585 ✓
	28160	HM0019588 ✓
	28246	HM0021206 ✓
	28246	HM0021376 ✓
	28246	HM0021309 ✓
	28246	HM0018246 ✓
	28246	HM0018232 ✓
	28246	HM0019460 ✓
	28246	HM0019727 ✓
	28246	HM0019718 ✓
	28726	HM0030858 ✓
	28726	HM0030872 ✓
	28726	HM0029349 ✓
	28726	HM0029956 ✓
	28726	HM0029071 ✓
	28726	HM0028763 ✓
	28726	HM0028614 ✓
	28726	HM0028706 ✓
	28842	HM0029310 ✓
	28842	HM0029279 ✓
	28842	HM0029295 ✓
	28842	HM0029193 ✓
	28842	HM0029189 ✓

28842	HM0029230 ✓
28842	HM0029257 ✓
28842	HM0029254 ✓
29233	HM0029618 ✓
29233	HM0029979 ✓
29233	HM0029952 ✓
29233	HM0029285 ✓
29233	HM0029264 ✓
29233	HM0029232 ✓
29233	HM0029297 ✓
29233	HM0029231 ✓
29395	HM0030821 ✓
29395	HM0030879 ✓
29395	HM0030870 ✓
29395	HM0029418 ✓
29395	HM0029391 ✓
29395	HM0029347 ✓
29395	HM0030763 ✓
29395	HM0030723 ✓

<b>Quantity Single Lumen Cannulas Requested:</b>	0
<b>Quantity Hudson RCI Dual Lumen Cannulas Requested:</b>	10
<b>Quantity Airline Dual Lumen Cannulas Requested:</b>	N/A
<b>Quantity Original Roller Bag Requested:</b>	1
<b>Quantity New Roller Bag Requested:</b>	N/A
<b>Quantity Carrying Bags Requested:</b>	1
<b>Quantity of Isopropyl Alcohol Wipes Requested:</b>	1
<b>Quantity of Protocol Bracelets Requested:</b>	1
<b>Quantity of DVDs Requested:</b>	0
<b>Quantity of Spare Key Holders Requested:</b>	0
<b>Quantity of Spare Keys Requested:</b>	0

**Devices currently at the subject's home:** 10137 (PC20120165), 10138 (PC20120166), 10311 (PC20120233), 10312 (PC20120238)

<b>Minicylinder kits currently at the subject's home</b>	<b>Kit Number</b>	<b>Serial Number</b>
	20353	HM0025899
	20353	HM0025818
	20353	HM0022855

20353	HM0025858
20353	HM0022745
20353	HM0022812
20353	HM0022885
20353	HM0025550
20665	HM0028399
20665	HM0028401
20665	HM0028371
20665	HM0028051
20665	HM0028077
20665	HM0028397
20665	HM0028156
20665	HM0028106
20735	HM0030670
20735	HM0029165
20735	HM0030144
20735	HM0029255
20735	HM0030609
20735	HM0029628
20735	HM0030129
20735	HM0030020
25184	HM0019692
25184	HM0019549
25184	HM0019691
25184	HM0019686
25184	HM0019395
25184	HM0019652
25184	HM0019526
25184	HM0019682
31256	HM0028120
31256	HM0027433
31256	HM0028190
31256	HM0028013
31256	HM0027375
31256	HM0027336
31256	HM0028194
31256	HM0028200
31464	HM0029703 <sup>R</sup>
31464	HM0029195 <sup>R</sup>
31464	HM0028838 <sup>R</sup>
31464	HM0028963 <sup>R</sup>
31464	HM0028844 <sup>R</sup>

31464	HM0028833 R
31464	HM0028811 P
31464	HM0028813 R
31675	HM0011453 R
31675	HM0028793 R
31675	HM0013326 R
31675	HM0011089 R
31675	HM0028703 R
31675	HM0010856 R
31675	HM0028834 R
31675	HM0012369 R
31965	HM0026179 R
31965	HM0024272 R
31965	HM0022582 R
31965	HM0025428 R
31965	HM0023425 R
31965	HM0023410 R
31965	HM0024121 R
31965	HM0024140 R
32109	HM0027552 R
32109	HM0027559 R
32109	HM0027532 R
32109	HM0027564 R
32109	HM0027613 R
32109	HM0027575 R
32109	HM0027560 R
32109	HM0027607 A
32135	HM0029094
32135	HM0027497
32135	HM0027508
32135	HM0026987
32135	HM0028550
32135	HM0028503
32135	HM0028565
32135	HM0029639
33998	HM0023618 R
33998	HM0023563 R
33998	HM0024805 R
33998	HM0023706 R
33998	HM0023519 R
33998	HM0024779 R
33998	HM0023524 R
33998	HM0023622 R

34199	HM0026054 R
34199	HM0025311 R
34199	HM0026086 R
34199	HM0025723 R
34199	HM0025644 R
34199	HM0025196 R
34199	HM0026108 R
34199	HM0026011 R
34284	HM0025020 R
34284	HM0024898 R
34284	HM0025027 R
34284	HM0025029 R
34284	HM0024882 R
34284	HM0026610 R
34284	HM0025026 R
34284	HM0025002 R





## YOURWAY TRANSPORT/UNITED BIOSOURCE SIGNATURE SHEET AND RESPONSIBILITY LOG

Protocol: IK-7001-PAH-201		Principal Investigator: Vijay Balasubramanian		Site/Center ID: 01050		
Name (Please Print)	Title	General Responsibilities (Please see Legend for codes)	Signature	Initials	Dates of Responsibilities	
					From (dd/mm/yy)	To (dd/mm/yy)
Joseph Quirk	Driver	b.c.d		JQZ	22/11/13	22/11/13

The Yourway Transport and UBC individuals listed above are responsible for collecting selected subject data and other responsibilities as indicated under General Responsibilities. New or replacement staff should be added to the log as appropriate.

Principal Investigator Signature \_\_\_\_\_ Date \_\_\_\_\_

### LEGEND

Use legend to complete the “General Responsibilities” column. Please enter the letter(s) (i.e. a, c, j) in column that corresponds to the responsibilities of the individual. For responsibilities that are not already indicated in the legend, please add them in the empty spaces provided below.

a)	Protocol related procedures	e)	Ensure proper use of device by subject	i)	
b)	Delivery and return of drug/device	f)	Equipment maintenance	j)	
c)	Delivery of ancillary supplies	g)	Provide subject education	k)	
d)	Drug/Device accountability	h)	Review home storage of drug/device	l)	

DRIVER TRAINING LOG FOR IKARIA PROTOCOL IK-7001-PAH-201

The driver acknowledges that he/she has been trained in the proper delivery, set-up, and accountability of product for the Ikaria Pharmaceuticals Protocol IK-7001-PAH-201. Furthermore, the driver has been instructed on what to do in the event that a patient reports an adverse event.

Driver's Name (Print): Joseph Quirk  
Driver's Name (Sign): Joseph Quirk  
Date: (Day/Month/Year): 22 Nov 13

Sender: Bicare US - Bicare Global Clinical Supplies, Americas, 1041 West Bridge Street, Phoenixville, PA 19460, USA

<b>Icaria</b>	<b>Clinical Trial Material Receipt Form - Subject (CTMRF)</b>	<b>204026</b>
<b>IK-7001-PAH-201</b>		
<b>Subject No.</b> 01050001	<b>Jaime Gomez (Subject Name)</b>	<b>Consignment 010620</b>
<b>Site No.</b> 01050  Vijay Balasubramanian	3075 E. Floradora Fresno CA 93703 USA Tel.: 559-761-3005	<b>Request Date:</b> 24-Oct-2013  <b>Type of Shipment:</b> Re-Supply  <b>Visit:</b> Week 40

Shipment content				
Item	Quantity	Description	Batch Number	Expiry Date
1	6	Study Drug Kit containing 8 minicylinders	40450	25-Oct-2014

<b>Content for item #1:</b>	<b>Store:</b> Ambient
28160	28246
28726	28842
29233	29395

Fax to email to

Report generated (UTC): 24-Oct-2013 8:05

77993  
GJA 24 Oct 2013

Sender: Bilcare US - Bilcare Global Clinical Supplies, Americas, 1041 West Bridge Street, Phoenixville, PA 19460, USA

Ikaria	Clinical Trial Material Receipt Form - Subject (CTMRF)	204026
IK-7001-PAH-201		
Subject No. 01050001	Jaime Gomez (Subject Name)	Consignment 010620

Prepared by:

Name in block letters:

WILLIAM BOYD

Signature:

William Boyd

Date:

28 Oct 2013

Checked by:

Name in block letters:

CHRISTINE BURNS

Signature:

Christine Burns

Date:

28 Oct 2013

Fax to email to

Report generated (UTC): 24-Oct-2013 8:05

77993  
A.M. 24 Oct 2013

Sender: Bicare US - Bicare Global Clinical Supplies, Americas, 1041 West Bridge Street, Phoenixville, PA 19460, USA

Ikaria	Clinical Trial Material Receipt Form - Subject (CTMRF)	204026
IK-7001-PAH-201		
Subject No. 01050001	Jaime Gomez (Subject Name)	Consignment 010620

**Acknowledgment**

Shipment received in good condition? YES  NO  If NO, please comment below

Missing or damaged material? YES  NO  If YES, please comment below

Comment:

I certify, that the information above are accurate and complete:

Received by:

Name in block letters Joseph Quirk Signature Joseph Quirk Date 22 Nov 13

Fax to email to

Report generated (UTC): 24-Oct-2013 8:05

77993  
GJM 24 Oct 2013