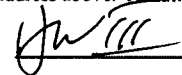


<b>UNITED STATES BANKRUPTCY COURT</b>		District of Delaware	<b>PROOF OF CLAIM</b>
Name of Debtor: <b>Graceway Pharmaceuticals, LLC</b>		Case Number: <b>11-13036</b>	
NOTE: This form should not be used to make a claim for an administrative expense arising after the commencement of the case. A request for payment of an administrative expense may be filed pursuant to 11 U.S.C. § 503.			
Name of Creditor (the person or other entity to whom the debtor owes money or property): <b>ATP, LLC</b>		<input type="checkbox"/> Check this box to indicate that this claim amends a previously filed claim.  Court Claim Number: _____ (If known)  Filed on: _____	
Name and address where notices should be sent: <b>ATP, LLC</b> <b>929 North Front Street, Wilmington, NC 28401</b> <b>Attn: General Counsel</b>  Telephone number: <b>(910) 251-0081</b>		<b>RECEIVED</b>  <b>DEC 15 2011</b>  <b>BMC GROUP</b>	
Name and address where payment should be sent (if different from above):     Telephone number:		<input type="checkbox"/> Check this box if you are aware that anyone else has filed a proof of claim relating to your claim. Attach copy of statement giving particulars.  <input type="checkbox"/> Check this box if you are the debtor or trustee in this case.	
<b>1. Amount of Claim as of Date Case Filed:</b> \$ <u>120,708.58</u>  If all or part of your claim is secured, complete item 4 below; however, if all of your claim is unsecured, do not complete item 4.  If all or part of your claim is entitled to priority, complete item 5.  <input type="checkbox"/> Check this box if claim includes interest or other charges in addition to the principal amount of claim. Attach itemized statement of interest or charges.		<b>5. Amount of Claim Entitled to Priority under 11 U.S.C. §507(a).</b> If any portion of your claim falls in one of the following categories, check the box and state the amount.  Specify the priority of the claim.  <input type="checkbox"/> Domestic support obligations under 11 U.S.C. §507(a)(1)(A) or (a)(1)(B).  <input type="checkbox"/> Wages, salaries, or commissions (up to \$11,725*) earned within 180 days before filing of the bankruptcy petition or cessation of the debtor's business, whichever is earlier – 11 U.S.C. §507 (a)(4).  <input type="checkbox"/> Contributions to an employee benefit plan – 11 U.S.C. §507 (a)(5).  <input type="checkbox"/> Up to \$2,600* of deposits toward purchase, lease, or rental of property or services for personal, family, or household use – 11 U.S.C. §507 (a)(7).  <input type="checkbox"/> Taxes or penalties owed to governmental units – 11 U.S.C. §507 (a)(8).  <input type="checkbox"/> Other – Specify applicable paragraph of 11 U.S.C. §507 (a)( ).	
<b>2. Basis for Claim:</b> <u>Services Performed</u> (See instruction #2 on reverse side.)		Amount entitled to priority: \$ _____	
<b>3. Last four digits of any number by which creditor identifies debtor:</b> _____  <b>3a. Debtor may have scheduled account as:</b> _____ (See instruction #3a on reverse side.)		*Amounts are subject to adjustment on 4/1/13 and every 3 years thereafter with respect to cases commenced on or after the date of adjustment.	
<b>4. Secured Claim</b> (See instruction #4 on reverse side.) Check the appropriate box if your claim is secured by a lien on property or a right of setoff and provide the requested information.  <b>Nature of property or right of setoff:</b> <input type="checkbox"/> Real Estate <input type="checkbox"/> Motor Vehicle <input type="checkbox"/> Other Describe:  <b>Value of Property:</b> \$ _____ <b>Annual Interest Rate</b> _____ %  <b>Amount of arrearage and other charges as of time case filed included in secured claim,</b> <b>if any:</b> \$ _____ <b>Basis for perfection:</b> _____  <b>Amount of Secured Claim:</b> \$ _____ <b>Amount Unsecured:</b> \$ _____		<b>6. Credits:</b> The amount of all payments on this claim has been credited for the purpose of making this proof of claim.  <b>7. Documents:</b> Attach redacted copies of any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements of running accounts, contracts, judgments, mortgages, and security agreements. You may also attach a summary. Attach redacted copies of documents providing evidence of perfection of a security interest. You may also attach a summary. (See instruction 7 and definition of "redacted" on reverse side.)  DO NOT SEND ORIGINAL DOCUMENTS. ATTACHED DOCUMENTS MAY BE DESTROYED AFTER SCANNING.  If the documents are not available, please explain:	
<b>Date:</b> <u>12/15/2011</u>		<b>Signature:</b> The person filing this claim must sign it. Sign and print name and title, if any, of the creditor or other person authorized to file this claim and state address and telephone number if different from the notice address above. Attach copy of power of attorney, if any.   <b>Hank Gerock, Senior Corporate Counsel</b>	

Penalty for presenting fraudulent claim: Fine of up to \$500,000 or imprisonment for up to 5 years, or both. 18 U.S.C.

Graceway Pharmaceuticals LLC



00105

BMC

**INSTRUCTIONS FOR PROOF OF CLAIM FORM**

*The instructions and definitions below are general explanations of the law. In certain circumstances, such as bankruptcy cases not filed voluntarily by the debtor, there may be exceptions to these general rules.*

**Items to be completed in Proof of Claim form****Court, Name of Debtor, and Case Number:**

Fill in the federal judicial district where the bankruptcy case was filed (for example, Central District of California), the bankruptcy debtor's name, and the bankruptcy case number. If the creditor received a notice of the case from the bankruptcy court, all of this information is located at the top of the notice.

**Creditor's Name and Address:**

Fill in the name of the person or entity asserting a claim and the name and address of the person who should receive notices issued during the bankruptcy case. A separate space is provided for the payment address if it differs from the notice address. The creditor has a continuing obligation to keep the court informed of its current address. See Federal Rule of Bankruptcy Procedure (FRBP) 2002(g).

**1. Amount of Claim as of Date Case Filed:**

State the total amount owed to the creditor on the date of the Bankruptcy filing. Follow the instructions concerning whether to complete items 4 and 5. Check the box if interest or other charges are included in the claim.

**2. Basis for Claim:**

State the type of debt or how it was incurred. Examples include goods sold, money loaned, services performed, personal injury/wrongful death, car loan, mortgage note, and credit card. If the claim is based on the delivery of health care goods or services, limit the disclosure of the goods or services so as to avoid embarrassment or the disclosure of confidential health care information. You may be required to provide additional disclosure if the trustee or another party in interest files an objection to your claim.

**3. Last Four Digits of Any Number by Which Creditor Identifies Debtor:**

State only the last four digits of the debtor's account or other number used by the creditor to identify the debtor.

**3a. Debtor May Have Scheduled Account As:**

Use this space to report a change in the creditor's name, a transferred claim, or any other information that clarifies a difference between this proof of claim and the claim as scheduled by the debtor.

**4. Secured Claim:**

Check the appropriate box and provide the requested information if the claim is fully or partially secured. Skip this section if the claim is entirely unsecured. (See DEFINITIONS, below.) State the type and the value of property that secures the claim, attach copies of lien documentation, and state annual interest rate and the amount past due on the claim as of the date of the bankruptcy filing.

**5. Amount of Claim Entitled to Priority Under 11 U.S.C. §507(a).**

If any portion of your claim falls in one or more of the listed categories, check the appropriate box(es) and state the amount entitled to priority. (See DEFINITIONS, below.) A claim may be partly priority and partly non-priority. For example, in some of the categories, the law limits the amount entitled to priority.

**6. Credits:**

An authorized signature on this proof of claim serves as an acknowledgment that when calculating the amount of the claim, the creditor gave the debtor credit for any payments received toward the debt.

**7. Documents:**

Attach to this proof of claim form redacted copies documenting the existence of the debt and of any lien securing the debt. You may also attach a summary. You must also attach copies of documents that evidence perfection of any security interest. You may also attach a summary. FRBP 3001(c) and (d). If the claim is based on the delivery of health care goods or services, see instruction 2. Do not send original documents, as attachments may be destroyed after scanning.

**Date and Signature:**

The person filing this proof of claim must sign and date it. FRBP 9011. If the claim is filed electronically, FRBP 5005(a)(2), authorizes courts to establish local rules specifying what constitutes a signature. Print the name and title, if any, of the creditor or other person authorized to file this claim. State the filer's address and telephone number if it differs from the address given on the top of the form for purposes of receiving notices. Attach a complete copy of any power of attorney. Criminal penalties apply for making a false statement on a proof of claim.

**DEFINITIONS****Debtor**

A debtor is the person, corporation, or other entity that has filed a bankruptcy case.

**Creditor**

A creditor is a person, corporation, or other entity owed a debt by the debtor that arose on or before the date of the bankruptcy filing. See 11 U.S.C. §101 (10)

**Claim**

A claim is the creditor's right to receive payment on a debt owed by the debtor that arose on the date of the bankruptcy filing. See 11 U.S.C. §101 (5). A claim may be secured or unsecured.

**Proof of Claim**

A proof of claim is a form used by the creditor to indicate the amount of the debt owed by the debtor on the date of the bankruptcy filing. The creditor must file the form with the clerk of the same bankruptcy court in which the bankruptcy case was filed.

**Secured Claim Under 11 U.S.C. §506(a)**

A secured claim is one backed by a lien on property of the debtor. The claim is secured so long as the creditor has the right to be paid from the property prior to other creditors. The amount of the secured claim cannot exceed the value of the property. Any amount owed to the creditor in excess of the value of the property is an unsecured claim. Examples of liens on property include a mortgage on real estate or a security interest in a car.

A lien may be voluntarily granted by a debtor or may be obtained through a court proceeding. In some states, a court judgment is a lien. A claim also may be secured if the creditor owes the debtor money (has a right to setoff).

**Unsecured Claim**

An unsecured claim is one that does not meet the requirements of a secured claim. A claim may be partly unsecured if the amount of the claim exceeds the value of the property on which the creditor has a lien.

**Claim Entitled to Priority Under 11 U.S.C. §507(a)**

Priority claims are certain categories of unsecured claims that are paid from the available money or property in a bankruptcy case before other unsecured claims.

**Redacted**

A document has been redacted when the person filing it has masked, edited out, or otherwise deleted, certain information. A creditor should redact and use only the last four digits of any social-security, individual's tax-identification, or financial-account number, all but the initials of a minor's name and only the year of any person's date of birth.

**Evidence of Perfection**

Evidence of perfection may include a mortgage, lien, certificate of title, financing statement, or other document showing that the lien has been filed or recorded.

**INFORMATION****Acknowledgment of Filing of Claim**

To receive acknowledgment of your filing, you may either enclose a stamped self-addressed envelope and a copy of this proof of claim or you may access the court's PACER system ([www.pacer.psc.uscourts.gov](http://www.pacer.psc.uscourts.gov)) for a small fee to view your filed proof of claim.

**Offers to Purchase a Claim**

Certain entities are in the business of purchasing claims for an amount less than the face value of the claims. One or more of these entities may contact the creditor and offer to purchase the claim. Some of the written communications from these entities may easily be confused with official court documentation or communications from the debtor. These entities do not represent the bankruptcy court or the debtor. The creditor has no obligation to sell its claim. However, if the creditor decides to sell its claim, any transfer of such claim is subject to FRBP 3001(c), any applicable provisions of the Bankruptcy Code (11 U.S.C. § 101 *et seq.*), and any applicable orders of the bankruptcy court.

## **ATTACHMENT TO ATP, LLC PROOF OF CLAIM**

ATP, LLC d/b/a/ PPD Medical Communications ("ATP") provided certain services for Graceway Pharmaceuticals, LLC ("Graceway") pursuant to that certain Services Agreement between Graceway and ATP dated December 21, 2009 as amended by that certain Amendment 1 to Services Agreement dated March 1, 2010 and Amendment 2 to Services Agreement dated September 27, 2010 (collectively the "Services Agreement"). A copy of the Services Agreement is attached to this proof of claim.

### **Unpaid Invoices**

ATP submitted the following invoices to Graceway for service fees and pass through expenses under the Services Agreement (the "Invoices"). Graceway has failed to pay the invoices. Copies of the Invoices are attached to this proof of claim.

<b>Date</b>	<b>Invoice Number</b>	<b>Amount</b>
September 14, 2011	23017010811	\$ 64,058.21
October 13, 2011	23017010911	\$ 60,696.82
	<b>Total</b>	<b>\$124,755.03</b>

### **Post Petition Services**

PPD estimates that approximately \$ 4,046.45 of the service fees covered by the Invoices were performed on or after September 29, 2011. The \$ 4,046.45 figure was calculated by dividing the total invoice for services provided in September 2011 by the number of days in September and then multiplying that by the total number of post petition days in September.

- Invoice for September services (\$60,696.82) / Days in September (30) = \$2,023.22
- Total post petition days in September (2) \* \$2,023.22 = \$4,046.45

### **Total Proof of Claim Amount**

PPD's total proof of claim amount is **\$120,708.58**. This was calculated by taking the total value of the Invoices (\$124,755.03) and subtracting the value of the post petition services (\$4,046.45).



**Remit payment to:**  
PPD Medical Communications  
12937 Collections Center Drive  
Chicago, Illinois 60693

**Bill To:** April Ryder, Accounts Payable  
Graceway Pharmaceuticals, LLC  
340 Martin Luther King Jr. Blvd, Ste 500  
Bristol, TN 37620

**Send all other correspondence to:**  
PPD Medical Communications  
2655 Meridian Parkway  
Durham, NC 27713

Client Number	Invoice Number	Terms of Payment	Invoice Date	Project
02861	23017010811	Due Upon Receipt or Per Contract	09/14/2011	230176501/2002 Graceway PCC/PAPVG

Description	Amount
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**PROFESSIONAL CONTACT CENTER SUPPORT - AUGUST 2011**

\$ 33,193.19

**ONGOING DIRECT COST**

Associate Director	11.50 hr(s) x \$174.00/hr=	\$ 2,001.00
Operations Supervisor	36.75 hr(s) x \$131.75/hr=	\$ 4,841.81
Nurse - Weekday (Mon-Fri)	349.50 hr(s) x \$74.25/hr=	\$ 25,950.38

**TECHNOLOGY COST**

IT Support/Maintenance		\$ 400.00
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**ADDITIONAL COSTS**

\$ 733.80

Telephone		\$ 69.30
Translation Services		\$ 100.24
Postage		\$ 435.11
Supplies		\$ 129.15

**PRODUCT SAFETY & PHARMACOVIGILANCE SUPPORT - AUGUST 2011**

\$ 25,958.75

Program Management		\$ 3,850.00
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**AGGREGATE REPORTING & ADDITIONAL PROGRAM MGMT**

Manager	22.75 hr(s) x \$156.75/hr=	\$ 3,566.06
Safety Specialist	30.75 hr(s) x \$124.25/hr=	\$ 3,820.69

Non-Serious Spontaneous Report Mgmt	48.00 case(s) x \$153.00/ea=	\$ 7,344.00
Serious Spontaneous Report Mgmt	2.00 case(s) x \$427.00/ea=	\$ 854.00
Literature AE Report Management	2.00 report(s) x \$456.00/ea=	\$ 912.00

**PRIOR MONTH ADJUSTMENT- JULY 2011**

Non-Serious Spontaneous Report Mgmt	27.00 case(s) x \$153.00/ea=	\$ 4,131.00
Serious Spontaneous Report Mgmt	3.00 case(s) x \$427.00/ea=	\$ 1,281.00

**TECHNOLOGY SUPPORT**

IT System Support		\$ 200.00
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**6% DISCOUNT**

\$ (1,557.53)

**ADDITIONAL COSTS**

\$ 685.00

Oracle AERS Access		\$ 425.00
Translation Services		\$ 260.00

**SAFETY TECHNICAL OPERATIONS SUPPORT - AUGUST 2011**

\$ 5,045.00

AERS Maintenance - monthly fee		\$ 2,625.00
Application Support - monthly fee		\$ 720.00
Subscription Licenses up to 5 Oracle AERS Users - monthly fee		\$ 1,700.00

**Invoice Questions?**

Please contact Phil Goldstein at 919-456-5878 for PCC.

Please contact Jeff Abate at 919-462-5630 for Safety.

Please contact Janet Marshall at 910-558-3450 for Safety Technical Operations.

**Wiring Instructions:**

PPD Development LP

Further crdt to: PPD Med Communications

Bank of America

Charlotte, NC 28254

ABA# 026009593 [Wire Transfer only]

ABA# 053000196 [ACH Transfer only]

Credit Acct# 000696217456

**Invoice Total: \$ 64,058.21**

Any meals and entertainment expenses included in the above total are subject to the 50% limitations imposed by Section 274(n) of the Internal Revenue Code.



Remit payment to:  
PPD Medical Communications  
12937 Collections Center Drive  
Chicago, Illinois 60693

Bill To: April Ryder, Accounts Payable  
Graceway Pharmaceuticals, LLC  
340 Martin Luther King Jr. Blvd, Ste 500  
Bristol, TN 37620

Send all other correspondence to:  
PPD Medical Communications  
2655 Meridian Parkway  
Durham, NC 27713

Client Number	Invoice Number	Terms of Payment	Invoice Date	Project
02861	23017010911	Due Upon Receipt or Per Contract	10/13/2011	230176501/2002 Graceway PCC/PAPVG

<b>Description</b>	<b>Amount</b>
--------------------	---------------

**PROFESSIONAL CONTACT CENTER SUPPORT - SEPTEMBER 2011**

\$ 30,007.19

**ONGOING DIRECT COST**

Associate Director	10.50 hr(s) x \$174.00/hr=	\$ 1,827.00
Operations Supervisor	31.50 hr(s) x \$131.75/hr=	\$ 4,150.13
Nurse - Weekday (Mon-Fri)	318.25 hr(s) x \$74.25/hr=	\$ 23,630.06

**TECHNOLOGY COST**

IT Support/Maintenance		\$ 400.00
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**ADDITIONAL COSTS**

Telephone	\$ 48.39	\$ 377.94
Translation Services	\$ 89.50	
Postage	\$ 240.05	

**PRODUCT SAFETY & PHARMACOVIGILANCE SUPPORT - SEPTEMBER 2011**

\$ 26,395.62

Program Management	\$ 3,850.00
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**AGGREGATE REPORTING & ADDITIONAL PROGRAM MGMT**

Manager	31.75 hr(s) x \$156.75/hr=	\$ 4,976.81
Safety Specialist	51.25 hr(s) x \$124.25/hr=	\$ 6,367.81
Safety Administrator	2.00 hr(s) x \$74.00/hr=	\$ 148.00

Non-Serious Spontaneous Report Mgmt	54.00 case(s) x \$153.00/ea=	\$ 8,262.00
Serious Spontaneous Report Mgmt	5.00 case(s) x \$427.00/ea=	\$ 2,135.00
Literature AE Report Management	1.00 report(s) x \$456.00/ea=	\$ 456.00

**TECHNOLOGY SUPPORT**

IT System Support	\$ 200.00
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6% DISCOUNT	\$ (1,583.74)
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**ADDITIONAL COSTS**

Oracle AERS Access	\$ 425.00	\$ 454.81
Postage	\$ 29.81	

**SAFETY TECHNICAL OPERATIONS SUPPORT - SEPTEMBER 2011**

\$ 5,045.00

AERS Maintenance - monthly fee	\$ 2,625.00
Application Support - monthly fee	\$ 720.00
Subscription Licenses up to 5 Oracle AERS Users - monthly fee	\$ 1,700.00

**Invoice Questions?**

Please contact Phil Goldstein at 919-456-5878 for PCC.

Please contact Jeff Abate at 919-462-5630 for Safety.

Please contact Janet Marshall at 910-558-3450 for Safety Technical Operations.

**Wiring Instructions:**

PPD Development LP

Further crdt to: PPD Med Communications

Bank of America

Charlotte, NC 28254

ABA# 026009593 [Wire Transfer only]

ABA# 053000196 [ACH Transfer only]

Credit Acct# 000696217456

**Invoice Total: \$ 60,696.82**

Any meals and entertainment expenses included in the above total are subject to the 50% limitations imposed by Section 274(n) of the Internal Revenue Code.

## SERVICES AGREEMENT

This Services Agreement (the "Agreement"), made this 21<sup>st</sup> day of December 2009 (the "Effective Date"), by and between ATP, LLC, d/b/a PPD Medical Communications, a North Carolina limited liability company with its principal executive offices located at 2655 Meridian Parkway, Durham, North Carolina 27713 (hereinafter referred to as "PPD") and Graceway Pharmaceuticals, a Delaware Limited Liability Company, with its principal executive offices located at 340 Martin Luther King, Jr., Blvd., Ste. 500, Bristol, Tennessee 37620 ("CLIENT").

WHEREAS, PPD is in the business of providing certain professional services to its Clients and represents that it has the necessary personnel, expertise, and experience to provide such services; and

WHEREAS, CLIENT wishes to retain the services of PPD to perform certain Professional Contact Center and Post-Approval Pharmacovigilance services in connection with CLIENT's pharmaceutical business; and

WHEREAS, PPD is willing to provide such services to CLIENT in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the parties agree as follows:

### 1. Services.

1.1 Services to be Provided by PPD. PPD hereby agrees to provide to CLIENT the services identified and described in Exhibit A attached to this Agreement (the "**Services**"). PPD shall perform the Services in compliance with (i) the terms and conditions of this Agreement; and (ii) all applicable laws, rules and regulations. CLIENT agrees that PPD is responsible only for those Services set forth in Exhibit A.

1.2 Applicability and Hierarchy of Terms. In the event of a conflict between the terms provided in any Exhibit hereto and the terms of this Agreement, the terms of this Agreement shall prevail.

1.3 Out of Scope. In the event that PPD is requested or required to perform services that are not specifically provided for in this Agreement (the "Out of Scope Services"), such Out of Scope Services and a compensation schedule therefore (the "Out of Scope Agreement") must be mutually agreed upon by the parties in writing prior to the provision of said Services. The Out of Scope Agreement shall constitute an amendment to this Agreement and the Out of Scope Services set forth therein shall be deemed to be Services as that term is used in this Agreement.

1.4 Quality Assurance. CLIENT has the authority to audit PPD procedures which relate to CLIENT and which materially impact PPD's role in fulfilling Services for CLIENT in accordance with established quality assurance procedures. CLIENT may audit PPD at any time during regular business hours at its discretion and agrees to give at least three (3) business days notice to PPD. Such audits may include but are not limited to PPD procedures, files, and records associated with

the Services. Should CLIENT's audit require any corrective action on the part of PPD, PPD shall respond to CLIENT in writing within thirty (30) days.

1.5 Use of Copyrighted Materials. If in connection with Services, CLIENT requests PPD to make and/or distribute copies of copyrighted materials such as journal articles or excerpts from publications, CLIENT agrees to pay the cost of any copyright fees incurred by PPD that are necessary for PPD to produce and distribute such copies. PPD shall receive prior authorization from CLIENT before incurring copyright fees on CLIENT's behalf. CLIENT shall indemnify PPD for any and all damages, losses, costs, including, without limitation, reasonable attorneys' fees, which PPD incurs as a result of making and/or distributing copyrighted material pursuant to CLIENT's request.

1.6 FDA Issues. Promptly upon receipt (i.e., within one business day), PPD shall provide CLIENT with a copy of any correspondence or notice it receives from the US Food and Drug Administration ("FDA"), or other governmental entity including but not limited to any request for Post-Market Surveillance Auditing by Health Canada – Health Product and Food Branch Inspectorate, directly relating to products or services covered by this Agreement. Further, PPD agrees to cooperate with CLIENT, if requested, in corresponding with the FDA or in filing any documents with respect to the products covered by this Agreement, as CLIENT deems necessary or desirable. Such services will be invoiced on a monthly basis at actual hours worked according to the rates associated with staff performing the services. PPD further agrees to provide CLIENT with summaries of any inspection by the FDA or other governmental entity, as well as any findings or correspondence of the FDA or other governmental entity directly related to any services or products governed by this Agreement. If possible, prior to submitting any documentation or other correspondence to FDA or other governmental entity directly related to any services or products governed by this Agreement, including but not limited to a form FDA 483, PPD agrees to provide CLIENT the opportunity to review and timely comment on any and all submissions. PPD shall forward to CLIENT a final copy of any and all submissions to FDA or other governmental entity as it relates to this Agreement.

1.7 MedDRA and WHODrug Dictionary Licenses. The parties acknowledge that MedDRA and Uppsala Monitoring Centre product licenses are required by all parties who wish to distribute or receive MedDRA or WHODrug dictionary terminology. Each party represents and warrants that it possesses a current MedDRA and/or Uppsala Monitoring Centre product license. In the event CLIENT requests that PPD perform services which require PPD to distribute MedDRA terminology or WHODrug dictionary to third parties, CLIENT shall be responsible for ensuring that all such third parties possess the necessary MedDRA and/or Uppsala Monitoring Centre product licenses.

## **2. Compensation and Payment.**

2.1 Resource Costs. CLIENT shall pay PPD for all Services performed under this Agreement in accordance with the rates for such Services set forth in Exhibit B ("**Direct Fees**"). For Services billed on an hourly basis, CLIENT shall compensate PPD for performance of services rendered by PPD pursuant to this Agreement on a time of staff hourly rate basis, with that hourly rate, based on the number of hours spent in one-fourth (¼) hour increments, covering associated staff compensation, fringe and employee benefits, general expenses, overhead, and taxes and the administration of such. Such rates shall also apply to staff time required for travel when off-site travel is requested by CLIENT. For the avoidance of doubt, when staff of PPD are on-site at CLIENT location, those staff members will be billed to CLIENT based upon actual time spent in a work day rather than on a twenty-four (24) hour day basis.

Terms used in Exhibit B shall have the following meanings: "Crisis" shall mean any circumstance that results in or is anticipated to cause a significant increase in call volume, necessitating additional coverage. These circumstances include, but are not limited to press releases, drug recall, drug tampering, professional journal articles, and major announcements at national health care related meetings. In the case of a Crisis, staff will be added only upon approval from CLIENT. "Holiday" shall mean those days, as listed in Exhibit B that PPD provides services to CLIENT. CLIENT shall also reimburse PPD for all out-of-pocket expenses incurred in connection with the performance of the Services, including, without limitation, investigator grants and fees, travel expenses, shipping and postage costs, copying and printing fees, copyright fees, third party drug storage and distribution fees, required Institutional Review Board or similar board or committee fees, and other "pass through" expenses reasonably expected to be incurred in connection with performing the Services (collectively, the "**Pass Through Costs**"). The Fee Schedule attached as Exhibit B may be revised by PPD on an annual basis after December 31, 2010. If PPD decides to revise Exhibit B, PPD shall provide CLIENT with the revised Fee Schedule reflecting the new rates, which revised Fee Schedule shall be attached hereto and incorporated by amendment herein. In the event PPD does not desire to revise Exhibit B, both parties agree that PPD may continue to provide services as described herein pursuant to the most recent rates per Exhibit B until PPD desires to revise Exhibit B, at which point PPD and CLIENT shall proceed with the revision process as described above.

2.2 Noncancelable Obligations. Upon termination of this Agreement pursuant to Section 3 below, CLIENT shall pay PPD all Direct Fees and Pass Through Costs for all Services performed through the termination date and applicable wrap-up period. Promptly upon sending or receiving notice of termination of this Agreement for any reason, PPD shall use all reasonable efforts to minimize any further costs and to promptly cancel all cancelable commitments. In addition, CLIENT shall reimburse PPD for all future non-cancelable obligations to third parties (where such obligations were created as a result of a Project being authorized by the CLIENT). Any funds held by PPD which shall be shown by CLIENT to be unearned at the date of termination shall be returned to CLIENT within forty-five (45) days after the termination date of this Agreement, whichever is applicable.

2.3 Pre-Execution Services. In the event CLIENT requests PPD to begin providing Services prior to the execution by CLIENT of an Out of Scope Agreement as referenced in Section 1.3 above, or other mutually agreed upon writing, CLIENT agrees that PPD shall be compensated on a time and materials basis for Services performed in accordance with the PPD Proposal for said Services.

2.4 Billing and Payment. PPD shall submit to CLIENT a monthly invoice describing the Services performed, the charges for such Services and all Pass Through Costs paid by PPD. CLIENT shall pay each monthly invoice within thirty (30) days of receipt of said invoice.

2.5 Payments. All payments to PPD under this Agreement shall be made as follows:

PPD Medical Communications  
12948 Collection Center Drive  
Chicago, IL 60693  
Tax ID#:74-2325267

2.6 Taxes. All taxes and any penalties thereon imposed on any payment made by CLIENT to PPD shall be the responsibility of PPD.



### 3. Term and Termination.

3.1 Term. The term of this Agreement shall commence upon execution of this Agreement by both parties and shall continue unless terminated according to Section 3.3.

*32 and*

*mmB  
04 Jan 2010*

3.2 Termination. This Agreement may be terminated as follows:

3.2.1 By CLIENT or PPD without cause upon one hundred and twenty (120) days written notice to the other party.

3.2.2 By CLIENT or PPD, if the other party shall default in the performance of any term or condition of this Agreement (other than nonpayment of moneys owed), on sixty (60) days prior written notice to the other, specifying the nature of the default, unless such defaulting party shall (i) cure that default within the sixty (60) day period; or (ii) present the non-defaulting party a reasonable plan to cure such default and thereafter comply with such plan as determined by the non-defaulting party.

3.3 Insolvency. Either party hereto may terminate this Agreement immediately upon the occurrence of an "Insolvency Event" with respect to the other party. For purposes of this Agreement, "Insolvency Event" shall mean (1) a party or any of its subsidiaries shall commence a voluntary proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, or shall consent to any such relief or to the appointment of or taking possession by any such official in an involuntary case or other proceeding commenced against it, or shall make a general assignment for the benefit of creditors, or shall fail generally to pay its debts as they become due, or shall take any action to authorize any of the foregoing; (2) an involuntary case or other proceeding shall be commenced against a party or any of its subsidiaries seeking liquidation, reorganization or other relief with respect to it or its debts under bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case or other proceeding shall remain undismissed and unstayed for a period of sixty (60) days; or (3) an order for relief shall be entered against a party or any of its subsidiaries under the federal bankruptcy laws now or hereafter in effect.

3.4 Wind Down. Upon the termination of this Agreement, PPD shall cooperate with CLIENT to provide for an orderly wind-down of the Services provided by PPD hereunder. Upon termination of this Agreement, at CLIENT's request, PPD shall continue to provide services contemplated hereunder at the most recently agreed upon rates until such time as CLIENT has secured and validated an alternate supplier for services or ninety (90) days from the date of termination, whichever is sooner.

3.5 Provisions Surviving Termination. The obligations of the parties contained in Sections 2, 3.5, 4, 5, 6, 7, 8, 9, 10, 11.2, 11.4, 11.5, 11.6, 11.7 and 11.11 hereof shall survive termination of this Agreement.

#### **4. Personnel.**

Noninterference with Employees. Each party acknowledges that the other's employees have received special training and have expertise in rendering services and are a valuable and unique asset of such party's business. During the period this Agreement is in effect and for a one (1) year period following the termination of this Agreement, each party agrees that, without the prior written consent of the other, it shall not knowingly hire any person who has been under the employment of the other during the term of this Agreement nor shall it solicit any such person (i) to terminate his or her employment with such party or (ii) to become associated with the other or its affiliates. Nothing contained herein shall be construed as prohibiting either party from hiring an employee of the other party in the event such employee of the other party answers an advertisement for employment from a newspaper of general circulation or other medium provided the party does not specifically solicit such employee of the other party.

#### **5. Confidential Information.**

5.1 CLIENT Information. PPD shall treat all information obtained from CLIENT ("CLIENT Confidential Information") under this Agreement as the confidential and exclusive property of CLIENT.

5.2 PPD Confidential Information. CLIENT shall treat any PPD bids or proposals and all PPD Property (as hereinafter defined) (collectively, "PPD Confidential Information") as the confidential and exclusive property of PPD.

5.3 Use of CLIENT and PPD Confidential Information. Each party shall use the other's Confidential Information solely for the purposes contemplated by this Agreement and for no other purpose without the prior written consent of other. Neither party shall disclose Confidential Information of the other to any third party without first obtaining the written consent of other. Each party shall take reasonable steps to ensure that the other's Confidential Information shall not be used by its directors, officers, employees, agents, representatives and advisors ("collectively, "Agents"), except on like terms of confidentiality as aforesaid.

5.4 Exceptions to Confidential Information. The above provisions of confidentiality shall not apply to that part of disclosing party's Confidential Information which the receiving party is able to demonstrate by documentary evidence:

(i) was in the receiving party's possession prior to receipt from the disclosing party or is independently developed by the receiving party;

(ii) was in the public domain at the time of receipt from disclosing party;

(iii) becomes part of the public domain through no fault of the receiving party or its Agents;

(iv) is lawfully received by the receiving party from a third party having a right of further disclosure; or

(v) is required by law to be disclosed provided each party shall use reasonable efforts to inform the disclosing party prior to disclosure giving disclosing party reasonable

opportunity to file for a protective order if disclosing party should so desire and receiving party agrees to cooperate with disclosing party in such efforts.

5.5 Return of Information. Upon termination or expiration of this Agreement, or at the disclosing party's request, the receiving party shall return, and shall cause its Agents to return, all Confidential Information provided by the disclosing party in documentary form, or, at the disclosing party's request, destroy all or such parts of the disclosing party's Confidential Information as the disclosing party shall direct, including any copies thereof made by the receiving party or its Agents. Notwithstanding the foregoing, the receiving party may retain one (1) complete copy of the disclosing party's Confidential Information as is reasonably necessary for regulatory and legal compliance purposes and to prove compliance with the terms and conditions of this Agreement, subject to the ongoing obligation to maintain the confidentiality of such information.

5.6 Remedy. Each party acknowledges that disclosure or distribution of the other's Confidential Information or use of the information contrary to the terms of this Agreement may cause irreparable harm for which damages at law may not be an adequate remedy. Accordingly, the disclosing party hereunder may seek to enforce the provisions of this Agreement prohibiting disclosure or distribution of its Confidential Information or use thereof contrary to the provisions hereof in a court of competent jurisdiction, in addition to any and all other remedies available at law or in equity.

5.7 Privacy Laws. All information containing personal data shall be handled in accordance with all applicable privacy laws, rules and regulations, including, without limitation, the European Data Protection Directive [EC/95/46] and Health Insurance Portability and Accountability Act (HIPAA).

## **6. Intellectual Property.**

6.1 No License. Neither anything contained herein, nor the delivery of any information to a party hereto, shall be deemed to grant the receiving party any right or licenses under any patents or patent applications or to any know-how, technology or inventions of the disclosing party.

6.2 Client Property. Subject to Section 6.3 below, PPD hereby assigns to Client all rights PPD or its Agents may have in any invention, technology, know-how or other intellectual property which is (i) a direct and sole result of PPD's provision of the Services or (ii) specifically set forth as a deliverable hereunder, and PPD shall assist Client, at Client's sole cost and expense, in obtaining or extending protection therefore. PPD warrants that it has and will continue to have agreements with its Agents to effect the terms of this Section 6.2.

6.3 PPD Property. Client acknowledges that PPD possesses certain inventions, processes, technology, know-how, trade secrets, improvements, other intellectual property and other assets, including, without limitation, those related to data collection, data management processes, procedures and techniques, computer technical expertise and software (including codes) which have been independently developed without the benefit of any information provided by Client (collectively, the "PPD Property"). All PPD Property and improvements thereto are the sole and exclusive property of PPD, and Client shall have no right, title or interest therein.

## **7. Indemnification.**

7.1 **CLIENT Indemnity.** CLIENT shall indemnify, defend, and hold harmless PPD and its Agents from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, costs and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorneys' fees, expert witness fees, court costs, and amounts incurred by PPD under indemnity obligations imposed upon it by a third party provider to a Project where such third party provider has been approved by CLIENT, incurred in connection with any claim, demand, action, proceeding, investigation or hearing (collectively, a "***Claim***") directly or indirectly relating to or arising from this Agreement or any Services provided by PPD hereunder, including but not limited to, Services provided by PPD at the request of CLIENT yet prior to finalization of an amendment hereto; provided however, that CLIENT shall have no obligation of indemnity hereunder with respect to any Claim to the extent determined by a court of competent jurisdiction to have arisen from the negligence or intentional misconduct on the part of PPD or its Agents.

7.2 **PPD Indemnity.** PPD shall indemnify, defend and hold harmless CLIENT and its Agents from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, cost and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorney's fees, expert witnesses and court costs, incurred in connection with any Claim to the extent determined by a court of competent jurisdiction to have arisen from the negligence or intentional misconduct of PPD or its Agents. PPD additionally agrees to indemnify CLIENT pursuant to this §7.2 regarding any patent infringement claims filed or brought by any party asserting any of the mechanisms or materials used by PPD in the provision of the services contemplated hereunder infringe any patent rights of the third party or other party claiming rights by or through said third party.

7.3 **Indemnification Procedure.** Each indemnified party shall give the indemnifying party prompt notice of any Claim for which indemnification is sought hereunder. The indemnifying party shall have the right to control the defense and settlement of a Claim, provided the indemnifying party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the Claim, and the indemnified party shall reasonably cooperate in the investigation, defense and settlement of such Claim. Any indemnified party shall have the right to participate in, but not control, the defense and settlement of a Claim and to employ separate legal counsel of its own choice; provided, however, that such employment shall be at the indemnified party's own expense, unless (i) the employment thereof has been specifically authorized by the indemnifying party, or (ii) the indemnifying party has failed to assume the defense and employ counsel (in which case the indemnified party shall control the defense and settlement of such Claim). The costs and expenses, including reasonable fees and disbursements of counsel, incurred by any indemnified party in connection with any Claim shall be reimbursed on a monthly basis by the indemnifying party subject to refund in the event the indemnifying party is ultimately held not to be obligated to indemnify the indemnified party.

## **8. LIMITATION OF LIABILITY.**

**PPD SHALL NOT BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF), INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS OR ANTICIPATED SALES. TO THE FULLEST EXTENT PERMITTED BY LAW, AND NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, THE TOTAL**

LIABILITY, IN THE AGGREGATE, OF PPD AND ITS AGENTS, AND ANY OF THEM, TO CLIENT AND ANYONE CLAIMING BY OR THROUGH CLIENT, FOR ANY AND ALL CLAIMS, LOSSES, COSTS OR DAMAGES, INCLUDING WITHOUT LIMITATION, ATTORNEYS' FEES AND COSTS AND EXPERT-WITNESS FEES AND COSTS OF ANY NATURE WHATSOEVER OR CLAIMS EXPENSES RESULTING FROM OR IN ANY WAY RELATED TO THIS AGREEMENT FROM ANY CAUSE OR CAUSES SHALL NOT EXCEED THE TOTAL FEES RECEIVED BY PPD UNDER THIS AGREEMENT. IT IS INTENDED THAT THIS LIMITATION APPLY TO ANY AND ALL LIABILITY OR CAUSE OF ACTION HOWEVER ALLEGED OR ARISING, INCLUDING WITHOUT LIMITATION, NEGLIGENCE, PROFESSIONAL ERRORS AND OMISSIONS, BREACH OF CONTRACT, UNLESS OTHERWISE PROHIBITED BY LAW.

**9. Record Storage.**

9.1 Record Maintenance. If applicable, during the term of this Agreement, PPD shall maintain all materials and all other data obtained or generated by PPD in the course of providing the Services hereunder, including all computerized records and files. PPD shall cooperate with any reasonable internal review or audit by CLIENT and make available to CLIENT for examination and duplication, during normal business hours and at mutually agreeable times, all documentation, data and information relating to Services.

9.2 Record Maintenance After Expiration or Termination. Upon the expiration or termination of this Agreement other than for CLIENT's breach of required payment hereunder, all materials and all other data and information obtained or generated by PPD in the course of providing the Services hereunder (the "Records") shall, at CLIENT's option, be (i) delivered to CLIENT at its expense and risk to its offices identified herein in such form as is then currently in the possession of PPD, (ii) retained by PPD for CLIENT for a period of three (3) years at CLIENT's expense, or (iii) disposed of at CLIENT's expense, as directed by written request of CLIENT, unless the Records are otherwise required to be stored or maintained by PPD under applicable law. If PPD is required or requested to maintain and/or store the Records for a period beyond three (3) years after the termination or expiration of this Agreement, CLIENT shall reimburse PPD for its maintenance and storage costs. In no event shall PPD dispose of Records without first giving CLIENT sixty (60) days prior written notice of its intent to dispose of the Records. PPD shall be entitled at its expense to retain copies of the Records reasonably necessary for regulatory purposes or to demonstrate the satisfaction of its obligations hereunder, all subject to the confidentiality obligations set forth in Section 5 above.

**10. Debarment.**

PPD hereby certifies that it has not been debarred, and has not been convicted of a crime, which could lead to debarment, under the Generic Drug Enforcement Act of 1992. If PPD or any of its Agents who perform certain Services is debarred or receives notice of an action or threat of action of debarment, PPD shall immediately notify CLIENT of same. The debarment of PPD or any of its Agents (which are providing Services to CLIENT under this Agreement) that remains in place for a period of at least thirty (30) days shall be deemed to be a material breach of this Agreement, unless, with respect to the debarment of an Agent which is providing services to CLIENT hereunder, PPD is able to replace the Agent within such 30-day period, in which case the debarment of the replaced Agent shall not be a material breach of this Agreement.

## **11. Miscellaneous.**

11.1 Independent Contractor Relationship. PPD is and at all times shall be an independent contractor in the performance of this Agreement and is not authorized to bind CLIENT to any agreement or contract, or in any other manner, with any third party. PPD shall exercise control over its employees and agents and shall be solely responsible for the verification of identity and employment eligibility, for the payment of any wages, salaries, or other remuneration of its employees and agents, and for the payment of any payroll taxes, contributions for unemployment or workers compensation, social security, pensions, or annuities which are imposed as a result of the employment of PPD's employees and/or agents.

11.2 Publicity. Except as required by law, neither party shall use the name of the other party or of any Agent thereof for purposes of publicizing this Agreement or any Services performed hereunder, or for any other public disclosure purposes without the prior written consent of the other party.

11.3 Force Majeure. If either party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reason of strike, lockouts, labor troubles, restrictive governmental or judicial orders or decrees, riots, insurrection, war, acts of God, inclement weather or other reason or cause reasonably beyond such party's control (each a "Disability"), then performance of such act shall be excused for the period of such Disability. Any timelines affected by a Disability shall be extended for a period equal to that of the Disability and any necessary budget adjustments shall be mutually agreed upon by the parties. The party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability.

11.4 Insurance. CLIENT and PPD each will maintain insurance in types and amounts reasonably adequate to cover any liabilities arising out of its obligations hereunder, and, upon request, each party will provide to the other party a certificate of insurance showing that such insurance is in place, which certificate shall demonstrate the amounts, exclusions and deductibles of such insurance coverage.

11.5 Notices. Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date delivered if delivered (i) personally, (ii) on the first business day after the date sent if sent by recognized overnight courier, (iii) on the date transmitted if sent via facsimile (with confirmation of receipt generated by the transmitting machine) or (iv) on the second business day after the date deposited if mailed by certified mail, return receipt requested, postage prepaid. All notices to each party shall be sent to the address for said party set forth below:

If to PPD:                      PPD Medical Communications  
2655 Meridian Parkway  
Durham, NC 27713  
Attention: Vice President, Operations  
Tel: (919) 765-8300  
Fax: (919) 765-8353

If to CLIENT:                      Graceway Pharmaceuticals, LLC  
222 Valley Creek Boulevard  
Third Floor - Suite 300

Exton, Pennsylvania 19341  
Attn: Arlene Santhouse  
Sr. Director, Drug Information & Surveillance  
Tel: (267) 948-0438  
Fax: (267) 948-0501

With a Copy to:

Graceway Pharmaceuticals, LLC  
340 Martin Luther King, Jr., Blvd. Ste. 500  
Bristol, Tennessee 37620  
Attn: John C. Bowles  
Corporate Counsel  
Tel: (423) 274-2122  
Fax: (423) 274-2155

Either party may change its notice address by notice to the other party hereto in the form and manner provided in this Section 11.4

11.6 Governing Law. This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of the State of Delaware without reference to its conflicts of laws provisions.

11.7 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any party hereto under this Agreement will not be materially or adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement, a legal, valid and enforceable provision as similar in terms as to such illegal, invalid or unenforceable provision as may be legally permissible and reasonably acceptable to the parties herein.

11.8 Waiver. Any term or condition of this Agreement may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition. No waiver by any party hereto of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.

11.9 Amendments. No amendment, change or modification to this Agreement shall be effective unless in writing and executed by the parties hereto.

11.10 Assignment and Subcontracting. This Agreement may not be assigned by either party without the prior written consent of the other party; provided, however, that (i) a party hereto may assign this Agreement to a successor-in-interest to the party's business and (ii) PPD may assign this Agreement or subcontract all or part of the Services to be performed hereunder to an Affiliate of PPD provided PPD agrees to maintain full responsibility for the performance of the terms and provisions of this Agreement. "**Affiliate of PPD**" shall mean an entity which can

provide the Services and which controls, is controlled by or is under common control with PPD or PPD's parent company Pharmaceutical Product Development, Inc.

11.11 Arbitration. Except for disputes regarding breaches of Section 5 and the right to pursue the remedies set forth in Section 5.2 above, the parties hereby agree to submit any ~~dispute arising hereunder to binding arbitration pursuant to the Commercial Arbitration Rules of~~ the American Arbitration Association. The arbitration shall be conducted in Wilmington, North Carolina. The decision of the arbitrator or arbitration panel shall be final and binding upon the parties hereto and shall be enforceable by any court of competent jurisdiction.

11.12 Construction. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the parties and no rule of strict construction shall be applied against either party hereto.

11.13 Counterparts and Facsimile Signatures. This Agreement, and any subsequent amendment(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement. A facsimile transmission of this signed Agreement bearing a signature on behalf of a party shall be legal and binding on such party.

11.14 Entire Agreement. This Agreement, including all attachments and schedules attached hereto, constitutes the entire Agreement among the parties pertaining to the subject matter contained herein and supersedes any and all prior and contemporaneous agreements, representations, and understandings. No supplement to or modification of this Agreement shall be binding unless executed in writing by each of the parties hereto.

IN WITNESS WHEREOF, this Agreement has been executed and delivered by the parties hereto by their duly authorized officers as of the date first above written.

ATP, LLC

By: Vivian Broach  
Name: Vivian Broach  
Title: VP, Operations  
Date: 04 Jan 2010



GRACEWAY PHARMACEUTICALS, LLC

By: John A. Bellamy  
Name: JOHN A. A. BELLAMY  
Title: EVP / GENERAL COUNSEL  
Date: JANUARY 6, 2010



EXHIBIT A  
DESCRIPTION OF SERVICES

## **Professional Contact Center**

PPD will provide medical information contact center support through its PCC. Medical information contact center support services will include:

- Management of medical inquiries received via telephone and email from consumers, healthcare professionals and sales representatives located in the US and Canada. Inquiries ~~not able to be managed using resources approved for use by PPD~~ will be triaged to Graceway per mutually agreed upon processes.
- Initial recognition and documentation of adverse event reports. Upon recognition of a potential adverse event PPD will document the report and submit it to PPD's Post-Approval PVG department, Graceway or Graceway's designee for continued processing per mutually agreed upon procedures. Procedures will include reconciliation processes.
- PPD will provide Graceway a daily notification of all new cases that require investigation. PPD will provide Graceway a weekly confirmation report that outlines Open, Pending, and recently Closed product quality complaint cases within IRMS. During the first week of each month, PPD shall provide Graceway with a detailed monthly report for the product quality complaint services (e.g. complaint types, volumes, refund & replacement).
- Initial recognition and documentation of product complaint reports. Upon recognition of a potential product complaint, PPD will document the report and submit it to Graceway or Graceway's designee for continued processing per mutually agreed upon procedures. PPD will provide fulfillment services for mailers associated with a product complaint. Procedures will include outbound follow-up calls as appropriate and reconciliation processes. Details of all product complaints reported to PPD must be reported to Graceway within twenty-four (24) hours.
- Fulfillment of approved letters and literature, as needed. Graceway and PPD will determine the most efficient methods by which PPD will be supplied with letterhead stationery, envelopes and literature needed for fulfillment purposes. PPD will respond to all requests within two business days of receipt, except in the event this time needs to be extended due to unavailability of literature or fulfillment supplies.
- PPD will make available for review by Graceway, at Graceway's request, recordings of customer service calls.
- Customer satisfaction surveys shall be created by PPD with Graceway concurrence and dispatched by PPD to a random sample of customer contacts in order to evaluate factors such as satisfaction with the information provided and customer satisfaction with the service responses.
- Graceway reserves the right to conduct pretext calling to monitor PPD's compliance with this Agreement.
- Graceway shall be informed of all changes to PPD's internal standard operating procedures related to this Agreement, it being understood that in no event shall PPD implement any such changes which affect the standard operating procedures of the Graceway program and / or PPD's compliance with this Agreement without Graceway approval.
- PPD shall respond to incidents causing an interruption or degradation in the services described in this Agreement according to their severity. Business critical problems with major impact or serious outages require notification to Graceway.

## **Record Retention**

PPD shall retain records of its activities in providing the services to Graceway for a period of ten (10) years for the product quality complaint documentation.

### Quality Assurance

PPD shall randomly audit a certain percentage of the product quality complaint cases handled by the drug safety officers in accordance with PPD's standard operating procedures.

Hours of operation for the Graceway medical information contact center program will be from 9:00 am to 6:00 pm ET, Monday through Friday. Voicemail will be established to capture calls during overflow or, if desired, outside of normal business hours. Hours may be modified as mutually agreed upon in writing by Graceway and PPD. Hours of operation do not include PPD holidays.

PPD may manage support for multilingual customers by recruiting and hiring multilingual staff who will be dedicated to Graceway's program. Alternatively, PPD can provide multilingual call center support by utilizing AT&T Language Line's Certified Medical Interpretation Service and/or other similar services that provide rapid access to online translators. Our staff are connected within seconds to interpreters fluent in up to 140 different languages to facilitate communication with the caller. This has proven to be a highly effective, cost-efficient option for many of our clients.

PPD has general standard operating procedures (SOPs) in place to support contact center services. General SOPs include Management of Procedural Documents, Training Program, Quality Assurance Program, Change Control and Disaster Readiness.

PPD will collaborate with Graceway to develop and gain approval of program-specific SOPs and operating guidelines. These documents may include, but are not limited to, the following topics:

- Inquiry Management Process
- Fulfillment Process
- Adverse Event Report Process
- Product Complaint Report Process

During program implementation, PPD will collaborate with Graceway to establish parameters for program metrics and reporting requirements. PPD can develop Web-based, password-protected reporting upon request. PPD typically reports the following:

- Weekly/monthly operational performance including total number of inbound inquiries and outbound calls, abandonment rate, average speed to answer and average handle time
- Nature of inquiry and resolution (e.g., verbal response only, written follow-up)
- Ad hoc reporting as required. Additional reporting will be billed based on time and materials.

### **Post-Approval Pharmacovigilance**

#### Individual Case Safety Reports

Hours of operation for the Post-Approval PVG portion of the program will be from 9:00 am to 5:00 pm ET, Monday through Friday. Hours of operation do not include PPD holidays.

Adverse events may be received via facsimile on an AE Intake Form from PPD's PCC, Graceway or other Graceway designees at any time via a 24-hour fax line or other electronic means. PPD will retrieve and process cases during normal business hours. PPD's Post-Approval PVG team will process initial reports according to PPD SOPs that, at minimum, include all four essential components for AE reportability plus the date of awareness.

For US spontaneous, non-serious adverse event reports, PPD will perform the following tasks:

- Assess AEs for reportability, seriousness and labeledness criteria and screen for duplicate AE reports
- Enter the cases into Oracle AERS and write the narrative
- Code AEs utilizing MedDRA in accordance with Graceway standards
- Perform up to 20% peer QC on the four required data elements for reportability, seriousness and date of awareness and perform up to 3% manager QC
- Notify Graceway on a weekly basis of all reports received for the calendar week
- Conduct follow-up
  - Details on when follow-up will be requested is in the Follow-Up chart on the next page
  - If required, two attempts will be made
  - The case will be closed after receipt of follow-up or after the second attempt, whichever comes first

For US spontaneous serious adverse event (SAE) reports, PPD will perform the steps above with the following additions/changes:

- Complete 100% peer QC of SAE reports with respect to the source documentation and MedWatch 3500A form and up to 3% manager QC
- Conduct follow-up
  - Expected Cases
    - Details on when follow-up will be requested is in the Follow-Up chart on the next page
    - If required, two attempts will be made
    - The case will be closed after receipt of follow-up or after the second attempt, whichever comes first
  - Unexpected Cases
    - Details on when follow-up will be requested is in the Follow-Up chart below
    - If required, three attempts will be made
    - Follow-up will be requested within five calendar days
    - The case will be closed after receipt of follow-up or after the third attempt, whichever comes first

PPD understands that Graceway will maintain ICSR medical review in-house and submit all ICSRs to the appropriate regulatory agencies.

Please refer to the budget estimate for associated costs; Graceway will be invoiced the unitized fee for each initial case and each time additional or follow-up information requires a case to be re-opened (after a report is finalized) and processed through the AE workflow.

#### Follow-Up

<b>Type A Non-Serious Expected Reports</b>	<b>Type B Non-Serious Unexpected or Serious Expected Reports</b>	<b>Type C Serious Unexpected Reports* or AEs of Interest (Including pregnancy)</b>
Drug	Type A plus	Type A and B plus
Identifiable reporter	Dose of company drug	Dose, regimen, indication of con meds
Identifiable patient	Indication of company drug	Lab results

Adverse event (AE)	Stop/Start date of company drug	Special treatment
	Full description of AE, including onset	If fatal, autopsy report
	Outcome, including sequelae	If pregnancy, follow specific procedures
	Dechallenge/Rechallenge	
	Serious criteria	
	Con meds or diseases	
	If hospitalized, discharge summary	

\* Literature case follow-up will be done 'as needed' based on medical judgment; included in price quote.

#### Performing duplicate case checks in Oracle AERS before data migration completion

As part of the migration process being performed by CSS Informatics, Graceway AE data will be moved from the IRMS database to temporary Oracle database tables after being exported. While the data migration to Oracle AERS is being completed, a duplicate case check can be performed on the temporary Oracle database tables to determine if reports are initial, follow-up or exact duplicates.

A query will be created that implements the duplicate case check algorithm, most likely in the form of a SQL script or pl/sql that can be executed in SQL\*Plus or a similar application. The script will accept parameters of the data to be checked (Country, Product, etc). For any duplicates found, a listing will be returned containing the IRMS Case ID and other case data required to complete the duplicate check.

During this transition period, two potential duplicate search options exist. The first is for PPD's PCC to perform the duplicate check on Post-Approval PVG's behalf should they have access to the AE module within IRMS. The second is for a PPD Safety Specialist to search the output tables for each new case as described above. For either option, should a duplicate be found, PPD will request case details (e.g., completed MedWatch 3500A form with submission date) from Graceway for confirmation of the duplicate report or to process the follow-up information. Due to the complexities involved with follow-up reports prior to full migration, PPD may need to manually enter the originally submitted report and then begin processing the follow-up information. Additional case handling outside of routine ICSR processing listed above during this transition period will be billed on a time and materials basis at the Safety Specialist hourly rate as part of Program Management. Once the migration is complete, this manual process will no longer be in effect and Graceway will be invoiced the unitized fee for case processing and routine Program Management support.

#### Aggregate Reports

PPD understands that Graceway will be requesting waivers (or has requested waivers) to submit periodic safety update reports (PSURs) to all required health authorities, including the FDA. PPD has provided information for annual PSUR reports as our experience has shown that the FDA traditionally grants waivers for the report but not always to change the reporting schedule.

### Periodic Safety Update Reports

Graceway will, in a timely manner, provide PPD with all known relevant data pertaining to the product(s) in English, including, but not limited to, data lock dates and submission schedules and safety information from all marketing partners.

PPD will prepare an ICH E2C-compliant draft PSUR and forward to Graceway for review within 30 calendar days of data lock. Graceway will review and provide any comments back within 40 calendar days of data lock. PPD will submit the final PSUR to Graceway within 55 calendar days of data lock for Graceway to submit to the appropriate regulatory agencies.

PPD understands that Graceway will be responsible for medical review and submission of the PSURs to the appropriate regulatory agencies.

Pricing for aggregate reports depends upon several factors, including the complexity of the product and the volume of reports for the reporting interval; therefore, PPD has prepared a three-tier cost estimate.

- Tier 1: No adverse events received during the reporting period; minimal Safety Specialist time required.
- Tier 2: Small volume (<70 ICSRs) and medium complexity (no health agency requests or special topics to cover); moderate Safety Specialist time required.
- Tier 3: High volume (70+ ICSRs) and/or high complexity (may include health agency requests or special topics); extensive Safety Specialist time required.

For pricing estimates, PPD assumed 12 Tier 1 reports, 15 Tier 2 reports and three Tier 3 reports for the three-year contract term. Due to the nature and intricacies of aggregate reports, these tasks are billed based on the actual time taken to complete the report.

### Safety Literature Review

It is PPD's assumption that Graceway will conduct systematic searches of the global scientific literature for safety surveillance in accordance with all applicable regulatory requirements. Graceway will review all citations/abstracts/articles for reportable events and forward full-text articles identified as having reportable event(s) to PPD for processing. PPD will invoice literature reports on a per-case basis as noted in the attached budget summary.

PPD understands that Graceway will be responsible for procurement and translation of full-text articles, including compliance with all applicable copyright laws and copyright clearance fees.

### **CSS Informatics**

#### ASP Hosting Services

#### **ASP Service Summary**

- CSS Informatics ("CSSI") presents this Proposal whose cost estimates are based upon the project considerations described herein. CSSI reserves the right to modify this Proposal and cost estimate in the event of material and/or significant changes to the assumptions.
- CSSI will provide ASP Hosting Services for the Oracle® Life Sciences ("OLS") applications specified in the assumptions (Collectively, "Hosted Applications") for the period of time and for the number of users described in the assumptions.

### Assumptions

- Hosted Applications are as follows:
  - Oracle Adverse Events Reporting System ("AERS") v.4.5.1
- The ASP Hosting Service includes:
  - Use of hosted hardware and software (exclusive of the price of Software Licenses)
  - Set-up Activities, including installation, validation of the installation, and ensuring access to the hosted environment.
  - ASP Maintenance Activities related to the operation of the infrastructure, including ASP System Maintenance, ASP Technical Support and ASP Help Desk Support and Program Management.
  - Internal Application Support for Hosted Applications which includes technical and functional support activities not included in the ASP Maintenance Activities.
  - Service Closeout Activities
- Proposed hosting service duration is three years (36 months).
- Base hosting service access is for up to 10 (ten) client named users.
- The Set-up cost is for a single database instance - Production.
- CSSI will load MedDRA and WHODrug dictionaries.
- The primary hosted environment is located at our data center in RTP, North Carolina.
- Many technical Set-up and maintenance functions will be provided by CSSI's affiliate IT group, (hereinafter referred to as "IT").
- For AERS, the Set-up cost is for a single production schema, which can be shared by pre-approval and post-approval users. Oracle AERS supports both clinical study cases and post-marketing cases in the same environment. Additional non-production AERS schemas are included to support testing and training.
- Standard Application Support is available 8:00 AM to 5:00 PM ET.
- Infrastructure support is 24x7 as outlined below under the technical support.
- CSSI will provide OLS application licenses on a subscription basis
  - **Subscription Licenses:** Recently, CSSI and Oracle Corporation entered into an agreement which allows CSSI to sell OLS licenses on a monthly subscription basis to any ASP hosting clients. Oracle AERS subscription costing is \$340 per user per month with a minimum user base of five users and a minimum subscription timeframe of one year.
- Dictionary licenses/subscriptions, such as MedDRA™ and WHODrug™, shall be purchased directly by Client from vendors.
- Data migration activities are included within this proposal.
- Data migration assumptions are listed below in the *Data Migration* section.
- CSSI will provide the costing for the following Additional Services and Materials:
  - User Acceptance Test (UAT) Packages
  - UAT Execution
  - OLS Training

### Definitions

- "Oracle AERS Named User" ("AERS Named User") is one individual named person who has a designated Oracle AERS license and had rights to access and use CSSI's Oracle AERS ASP services. AERS Named Users can only be employees, agents, contractors or business partners of Client or its Affiliates. Client shall ensure that an agent, contractor or business partner of Client that is an AERS Named User shall be bound by substantially similar terms and conditions as Client, as contained in this Agreement for access and use of CSSI's ASP services. An AERS Named User shall only use CSSI's ASP services for internal business purposes of Client and shall not use CSSI's ASP services on behalf of any third party.

- "Hosting Service Startup": The Hosting Service will be deemed to have started when Client Users are able to access and use the Hosted Applications for testing or production use.

#### **Set-up Activities**

- Set-up Activities include all activities necessary to set up the hosting environment, install the hardware and software, validate the environment, set up networking connections, and ensure secure access by Named Users at Client site. IT will set up a dedicated database instance on an ASP shared database server. Access will be via dedicated application servers.
- Hosting Service will be deemed to have commenced when Client Users are able to access and use the Hosted Applications for testing or production use.
- IT typically requires up to a 90 day Set-up period after contract execution.
- Costs for hardware and software for the dedicated application servers and for the dedicated disaster recovery application servers for the Hosted Applications will be passed through to Client. This will include the hardware and base OS software (including maintenance for each year of hosting) for the hosted environment for the Hosted Applications.
- IT will install and complete the Installation Qualification and Operational Qualification (IQ/OQ) validation of the Hosted Applications on the dedicated database instance.
- The Hosted Applications will be maintained in a validated state according to CSSI's affiliate Standard Operating Procedures (SOPs) and Working Practice Documents (WPDs). These validation procedures include IQ and OQ of all hardware and software components. Once the system has been validated, standard change control procedures will be employed for all changes to the system.
- The validation procedures (IQ/OQ) require review and sign-off by CSSI's affiliate Computer Systems Validation Committee (CSV). This committee includes a Quality Assurance (QA) representative. In addition, QA performs internal audits as systems are validated. Finally, IT undergoes between 70 and 80 client audits per year. The Client has the right to audit on-site at any time (with reasonable notice).
- IT will set-up all internal networking technology, remote access, and firewall solutions, working with the Client's networking group as required.
- All host servers and internet access are protected with McAfee antivirus software. IT also runs Intrusion Detection Software (IDS) in the DMZ. Firewalls are monitored 24 hours a day, seven days a week, 365 days a year. Procedures are in place for escalating and resolving suspicious activities.

#### **ASP Maintenance Activities**

- System Maintenance
  - Maintenance activities includes all activities necessary to maintain the ASP infrastructure, such as network maintenance, system administration, database administration, application of patches/upgrades and regularly scheduled system backup
  - IT will provide maintenance of the servers and software according to standard procedures and processes. Regular upgrades and patches will be applied under IT change control procedures.
  - IT will maintain all hardware, software and databases in a validated environment.
  - IT operates the hosting environment under approved standard procedures and processes. Standard procedures cover all aspects of system management and database management including regularly scheduled backups, off site storage, record retention, and disaster recovery procedures.
  - CSSI will perform a single dictionary upgrade or load for MedDRA at most once every six (6) months, and for WHODrug, at most once per quarter, as part of the standard



monthly base fee for the production database. Additional dictionary loads or upgrades requested by Client will be an additional charge. The dictionary loads will include no impact analysis.

- If impact analysis is required, or if additional dictionary loads or upgrades are requested an agreement must be signed by both parties and they will be charged at current technical consulting rates.
  - CSSI will perform all aspects of system management and database management, including, but not limited to, regularly scheduled weekly and nightly backups, off site storage, record retention and disaster recovery procedures.
  - All databases are backed up nightly (hot backups nightly and cold backups once a week) and servers are also backed up nightly.
  - Nightly backups are stored securely in the computer room, while weekly backups are rotated to off-site secure storage. Secured, bonded off-site storage is maintained for all system backups and project data archives. System backups are retained for three (3) years; project data archives are retained indefinitely.
  - IT has an SOP for disaster recovery that provides disaster recovery plans for all of its critical systems. These processes are reviewed, updated and re-tested once every two (2) years.
  - All host servers and Internet access are protected with McAfee antivirus software. CSSI also runs IDS in the DMZ. Firewalls are monitored 24 hours a day, seven days a week, 365 days a year. Procedures are in place for escalating and resolving suspicious activities.
  - Hosted Applications will be maintained in a validated state according to IT SOPs and WPDs. These validation procedures include IQ and OQ of all hardware and software components. Once the system has been validated, standard change control procedures will be employed for all changes to the system.
  - Client has the right to audit on-site at CSSI at any time with reasonable notice.
- Technical Support
    - IT provides full 24x7x365 technical support and operation of the infrastructure under its SOPs and WPDs, including network management, systems administration and database administration.
    - IT has procedures in place to maintain all aspects of the computing environment. The hardware and software systems are constantly monitored for performance by specialized software. Regularly scheduled systems down times provide windows for both preventative maintenance and corrective actions to prevent system failure during operational hours.
    - Should a system failure occur, technical support is available 24x7 to evaluate the problem and return the system to proper operation. Monitoring software is installed to automatically alert (i.e., page) support personnel of issues. During the timeframe of 2 A.M. ET Monday through 2 A.M. ET Saturday, trouble calls are answered as received by Help Desk personnel who log the problem and alert the appropriate support personnel. During off hours, a voice mailbox is available that will automatically page qualified on-duty support staff. The trouble call will be responded to within 15 minutes after receipt to start the problem resolution process.
    - All hardware and software in the hosting environment is supported by 24x7 support contracts with vendors. IT will work with the vendors to correct problems and return the system to proper operation as quickly as possible. CSSI will manage such process and provide updates to Client as the process unfolds.

- Program Support
  - See Staffing Assumptions section of proposal (page 12)
- Help Desk Support
  - IT offers toll-free technical Help Desk support during normal business hours in the US and Europe. The Help Desk provides support for any issues related to the core hosting service. Application support issues are forwarded to the Program Manager and are covered by a separate cost structure (see Application Support below).

### **Internal Application Support**

Application Support includes functional support for the Hosted Applications for Client users for items not included in the ASP System Maintenance, Technical Support and Help Desk Support and Program Management. Standard Application Support is provided 8:00 AM to 5:00 PM ET. Such activities include but are not limited to:

- Application account creation, maintenance and modifications
- All database configuration changes (e.g. codelist, roles, profiles, etc.)
- Modifications to Oracle AERS workflow
- Functional advice or assistance in using the Hosted Applications
- Report creation or modification
- Other minor (approximately one to two hours to resolve or complete) support services as requested by Client. Services beyond two hours would require explicit Client written pre-approval and/or a separate schedule.

### **Service Closeout**

- Service closeout consists of activities associated with concluding ASP use, including network, system, and database administration. It also includes data export and archiving according to standard IT procedures.
- An Oracle Relational Database Management System (RDBMS) Export will be performed and the files provided to Client.

### Services in Addition to Hosting

#### **User Acceptance Test Packages**

While CSSI and IT will complete the installation and base validation, Client may choose to additionally perform their own user acceptance testing per Client SOPs and processes, especially if Client may be modifying and updating data within the Hosted Application. CSSI offers User Acceptance Test (UAT) packages consisting of test cases to target key functional areas of OLS applications covering a normal business process. It includes:

- Oracle AERS Short Test
  - Approximately 100 test cases of main AERS functions and 21 CFR Part 11 functions.
  - Standard Requirements (including 21 CFR Part 11).
  - Standard Traceability Matrix mapping Standard Requirements to Test Cases

#### **UAT Customization**

UAT materials can be further customized on a time and materials basis.

#### **UAT Execution**

UAT execution assistance is available on a time and materials basis.

UAT execution time estimates below are based on CSSI tester (or Client's experienced staff) executing the test scripts and one screen shot per test script. CSSI has quoted the execution time of the OC test scripts based on the standard execution and documentation. If additional screen shots or documentation are required by the Client's validation process, then the estimated number of days may increase.

#### Oracle AERS

- AERS Short Test - eight days

#### Training

See Training section of proposal (page 15)

#### Data Migration

Due to the limited information available concerning the source IRMS system, CSSI must make the following assumptions. The cost and time estimates may require modification if these assumptions /expectations change.

- Source system
  - IRMS (SQL Server based).
  - Only the adverse event module would need to be migrated.
  - Source system will be in use during migration activities.
  - The source IRMS system has not been customized.
  - The IRMS database is composed of the fields and tables as documented in *IRMS 5.8.3.0 and 5.8.3.1 Release Functional Specification Document* and *IRMS Adverse Events Guide*.
  - The source data contains reasonably consistent use of data fields.
  - As a source system schema was not available for review prior to developing this proposal, CSSI will assume a schema of moderate complexity.
  - The source data does not contain non-structured (free text) fields other than narrative and comment fields.
- Cases
  - There are approximately 18,500 postmarketing cases to migrate.
  - All cases are to be migrated using the same formats and rules.
  - Audit trail of cases will not be migrated.
  - No E2B electronic reporting records or cases are to be migrated.
  - All cases are in English.
- Migration
  - The event and history verbatim terms are coded to the same dictionary versions in the source and target systems.
  - No specific client SOPs or templates are required to be followed.
  - CSSI will be provided with an initial database export of the source data at least four and one half months before the expected completion of the migration. CSSI must receive an **initial export of the source data**, including related data, such as tables containing decodes of list values or product information, no later than **Oct 15, 2009** to complete the migration in March 2010.
  - A final database export will be provided at the time of cut-over to the Oracle AERS system.
  - CSSI will be responsible for the primary validation activities related to the data migration effort.
  - Follow-up cases entered in the Oracle AERS database before the migration is complete must not be overwritten by the legacy data during the migration.

## STAFFING ASSUMPTIONS

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### Program Management

PPD will provide Program Management support during the implementation and operational phases of the Graceway program. During program implementation, PPD recommends frequent and regularly scheduled interactions with key Graceway contacts to ensure a thorough understanding of expectations and to facilitate process development. During the operational phase, PPD will provide Program Management support which includes, but is not limited to, oral and written communication with Graceway, procedure and protocol development, procedure and protocol maintenance, report generation, training plan development and maintenance, staff training, staff supervision and development, quality assurance processes, consultative services, meeting preparation and participation, audit preparation, participation and follow-up, and communication with other third parties necessary for business operations. PPD will ensure that all team members are contracted to adhere to HIPAA, the FDA (21 CFR), as applicable, and all other relevant data protection legislation and professional and company confidentiality clauses.

### Professional Contact Center Staffing

PPD will utilize highly trained registered nurses for Graceway's program. After a thorough review of the proposed scope of services, Graceway's forecast and the assumptions listed in Appendix B, PPD recommends the staffing model detailed in the table below

Staff Member	FTE
Nurse	2.00
Operations Supervisor (HCP)	0.21

PPD utilizes IEX Total View (a call center workforce management tool) and other proprietary tools to determine the staffing levels needed to meet the desired service level goals. PPD will continuously monitor workload and will collaborate with Graceway to determine any need for staffing level modifications.

PPD will train an appropriate number of staff to support times when the regularly assigned staff members are not available (e.g., due to sickness or paid time off). This supplementary staff may also be used for business contingency purposes should inquiry volume spike for any reason.

PPD's Operations Supervisor will serve as the primary point of contact for Graceway for the medical information contact center program. The Operations Supervisor has primary responsibility for staff training, development and quality assurance monitoring, and will operate closely with contact center staff to maintain all service functions

A PCC Associate Director (AD) of Operations will ensure contract compliance and corporate-level resource support. The AD will consult regularly with the Operations Supervisor during implementation, as well as during the operational phase of this program. Additionally, the AD will serve as a secondary contact point for Graceway.

The PCC staffing is displayed in the organizational chart below:

### **Post-Approval Pharmacovigilance Staffing**

PPD's Safety Specialists are highly trained healthcare professionals that are assigned to process ICSRs and prepare aggregate reports. PPD may utilize Safety Administrator staff to perform data entry, case distribution and document management activities with support from the Safety Specialists.

PPD will assign a Post-Approval PVG Manager to serve as the primary point of contact for Graceway. The Manager will operate closely with safety staff to maintain contracted service functions.

PPD will assign a Post-Approval PVG Associate Director (AD) to ensure contract compliance and corporate-level program resource support. The AD will consult regularly with the Manager during program implementation, as well as during the operational phase. Additionally, the AD will serve as a secondary contact point for Graceway.

PPD will bill the base implementation as referenced in the budget estimate; any cost incurred in excess of this amount will be communicated to Graceway ahead of time and billed at the hourly rate associated with the personnel performing the tasks.

Program management is billed on a monthly basis according to the attached budget. Program management time in excess of 24 hours per month will be billed at the hourly rate associated with the personnel performing the tasks.

PPD will train an appropriate number of staff to support times when the regularly assigned staff members are not available (e.g., due to sickness or paid time off). This supplementary staff may also be used for business contingency purposes should report volume spike for any reason.

Post-Approval PVG staffing is displayed in the organizational chart below:

## **CSS Informatics Staffing**

CSSI will assign a Program Manager as primary point of contact to Client and all Named Users for the purposes of support under the Agreement. The CSSI ASP Business Lead shall be responsible for working with Client to identify all ASP requirements and services required and coordinating across CSSI's project team to ensure all requirements are met. Written contact information will be provided to Client.

Numerous other technical and functional personnel are used, as necessary, in order to ensure that the set-up, implementation and ongoing maintenance activities are successfully addressed.

## **TRAINING**

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### **Professional Contact Center/Post-Approval Pharmacovigilance**

PPD demonstrates a commitment to providing employees with a solid foundation of knowledge through an extensive training program. Each employee is assigned a curriculum with applicable training requirements based upon the responsibilities of their position and the specific job functions they will perform. These requirements include courses from the PPD core training curriculum and departmental training, as well as training developed specifically for the Graceway program on which the employee works.

PPD will work with Graceway to develop a program-specific curriculum that may utilize a variety of training techniques including mentor training, self-study, role-playing, practical exercises and, where applicable, traditional classroom instruction. Content will be derived from client-specified and PPD-developed resources. Training time will vary based on the scope and magnitude of the program, technology requirements, number and complexity of products being supported, associated disease state information, and the scope of staff responsibilities. All staff assigned to the Graceway program will complete the program-specific curriculum prior to performing services.

It is PPD's assumption that Graceway will provide program-specific training materials and that training may be conducted jointly by Graceway representatives and PPD's program management. Alternatively, PPD will develop and conduct program-specific training on behalf of Graceway. PPD anticipates that Graceway will provide guidance regarding ex-US regulations for medical information support services during program-specific training. The availability of Graceway training materials will impact the PPD management team's ability to develop the program-specific curriculum and train staff in a timely and efficient manner.

PPD will collaborate with Graceway to develop a process for ongoing training, as well as training on updated/revised client-provided informational resources. Additional training after the implementation date will be conducted as needed and will be billed hourly at the rate of the staff participating.

### **CSS Informatics**

Standard OLS training for AERS consists of:

- Training will be delivered in English at Client site and is targeted to ensure all participants understand how to use the system for their particular business purposes.

- Training will follow the general methodology of slide presentations on each of the functional areas of the application, followed at the end of each section with practical exercises, where appropriate.
- OLS training for AERS consists of:
  - Training at Client site.
  - Instructor-led PowerPoint presentations with hands-on practices.
    - Client will receive an electronic color PDF copy of the PowerPoint presentation slides (two-slides-on-a-page format). **Client will be responsible for printing this material for each trainee attending the class.**
    - Client will receive electronic PDF copies of the practice materials. **Client will be responsible for printing this material for each trainee attending the class.**
    - **Black and white hardcopies of the practice materials and PowerPoint presentation slides (two slides-on-a-page format) (collectively "Classroom Materials") may be provided for an extra fee of \$100 per training day. Advance notice of one week will be required for delivery.**
  - Access to CSSI training database during the training.
  - Training Certificates will be produced by CSSI for each trainee upon completion of training.
  - Client is responsible for setting up
    - Training room with PCs connected to CSSI Training Database
    - Trainee machines with Windows® Internet Explorer®, Oracle® JInitiator, and Adobe® Acrobat Reader™
    - Trainer machine, with Windows Internet Explorer, Oracle JInitiator, Adobe Acrobat Reader, and Microsoft® Office PowerPoint®
    - Access to the internet so trainees and trainer can access the CSSI Oracle Clinical training database
    - White board for the trainer
    - Projector and screen – with the projector to be connected to the trainer's machine in order to display the presentation.

## **INFORMATION TECHNOLOGY**

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PPD's Medical Communications division has a dedicated in-house Information Technology (IT) department to support its Professional Contact Center and Post-Approval PVG infrastructure. The Director of IT will maintain primary accountability for systems installation, application development and implementation, and account management relating to technology and ongoing support. The operations account team will work closely with the IT team.

PPD has extensive standard operating procedures to govern the setup and administration of computer and telecom systems. These include procedures to manage the software development life cycle, data security, and disaster preparedness and recovery. PPD also maintains an extensive library of working practice documents to govern management of IT activities and support of individual computer systems.

PPD has specific procedures for emergency operations and disaster recovery plans for PPD critical systems. The core strategy for disaster recovery is utilization of duplicate internal data centers and resources at alternate PPD facilities. These disaster recovery plans are kept in a secured location on site and a copy is kept at our secured offsite storage facilities.

It is PPD's understanding that telephone inquiries will be directed to PPD through an existing Graceway toll-free number. For the purposes of this revised proposal, it is assumed Graceway will manage applicable call-forwarding technology and will assume the associated telecom charges. PPD has significant experience in working with multiple local and long distance telephone carriers to coordinate cost-effective telephone transfer solutions and can, if desired, acquire toll-free number(s) for use on this program and/or to facilitate the call-forwarding process. Such services will be billed as pass-through.

PPD's Budget Estimate contains a Monthly IT Support Fee, specific to the anticipated needs of this program. PPD's Monthly IT Support Fee includes routine support and management of the following, if applicable:

- PPD-provided hardware
  - Computer systems
  - Telephony
- PPD shared network resources
- PPD telephony and call- recording systems
  - Quarterly updates to telephone message scripting and/or programming
  - Ten (10) pre-defined holiday script changes per year
- General troubleshooting of client-provided hardware and/or applications
- PPD-Client network connectivity
  - Support/configuration of inter-company VPN
  - Support assistance of client-owned or –managed WAN
  - Administration of PPD firewall for either connection type

Should IT support outside of this scope be requested, PPD will provide a budget estimate to cover the required services. Out-of-scope IT support services will not be performed unless mutually agreed upon in writing.

### **Professional Contact Center Technology**

For this program, PPD will utilize a Graceway provided CRM (Customer Relationship Management) system. For the purposes of documenting customer interactions and generating fulfillment, PPD will have access to Graceway's IRMS system via a secure, encrypted network connection.

All calls within the Professional Contact Center are digitally recorded for quality assurance purposes.

### **Post-Approval Pharmacovigilance Technology**

PPD utilizes Oracle® AERS (Adverse Event Reporting System) as its in-house repository for electronic adverse event data. This validated, 21CFR Part 11-compliant system is configurable to meet individual client needs and is fully scalable to meet future portfolio growth. Each client has an established schema that includes only information related to their product(s) and adverse events. Only trained PPD staff have security access to view or enter data into the schema.

### **CSS Informatics Technology**

See Operational Assumptions section of proposal for detailed information regarding hosting and data migration services being performed.



## APPENDIX A – PROGRAM TIMELINES

The following dates are dependent upon a number of operational factors such as review and acceptance of this revised proposal, signing a Letter of Agreement, signing a contract, development of training materials, training, etc.

PCC Activity	Duration/Date
Letter of Agreement	05Oct09
Project Implementation	05Oct09 – 31Dec09
Staff Training	14Dec09 – 31Dec09
Information Technology Implementation & Testing	01Dec09 – 31Dec09
Finalize Contract	TBD
"Go Live" Date*	04Jan10

Post-Approval PVG Activity	Duration/Date
Letter of Agreement	05Oct09
Project Implementation	01Nov09 – 31Dec09
SOP Finalization/Approval	23Nov09 – 18Dec09
Staff Training	14Dec09 – 18Dec09
Information Technology Implementation – Non-hosted <ul style="list-style-type: none"><li>• Establish connectivity</li><li>• Set-up schema</li><li>• Test schema</li></ul>	01Nov09 – 31Dec09
Information Technology Implementation – Hosted <ul style="list-style-type: none"><li>• Establish connectivity</li><li>• Set-up schema</li><li>• Test schema</li></ul>	01Oct09 – 31Dec09
Finalize Contract	TBD
"Go Live" Date*	04Jan10

\*As January 1, 2010 is a PPD holiday, the Go Live Date is estimated to be January 4, 2010 as the first business day following the New Year's Day holiday.

## APPENDIX B – SERVICE PARAMETERS

PPD's revised proposal and budget estimate are based on the assumptions listed below. Any changes to the assumptions stated in these tables may impact service levels, budget and/or staffing levels. PPD will work to proactively notify Graceway of any scope change that may affect staffing and budget.

### Professional Contact Center Assumptions

Service Parameters	Metric
Service Level Goal	80/20
Average Monthly Call Volume	543
Average Handle Time (Talk + Wrap)	5 min.
Average Monthly Fulfillment Volume	109
Average Fulfillment Handle Time	5 min.
Average Monthly AE Volume	60
Average Handle Time AE Report	20 min.
Average Monthly PC Volume	43
Average Handle Time PC Report	16 min.
Average Training Time per Staff Member	40 hrs.

### Post-Approval Pharmacovigilance Assumptions

Service Parameters	Metric
Estimated Number of Spontaneous Non-Serious Reports per month	57
Estimated Number of Spontaneous Serious Reports per month	3
Estimated Number of Literature Reports per month	2
Number of Tier 1 ICH E2C PSURs for proposed contract term	12
Number of Tier 2 ICH E2C PSURs for proposed contract term	15
Number of Tier 3 ICH E2C PSURs for proposed contract term	3
<b>Training<sup>1</sup></b>	<b># Staff</b>
Manager, Post-Approval PVG (average training time of 20 hours)	1
Safety Specialist (average training time of 20 hours)	2
Safety Administrator (average training time of 11 hours)	1

Note 1: The initial staff training estimated for this program is noted above and reflected on the attached budget grid. Due to the small number of FTEs required on this program, an additional Safety Specialist will be trained as back-up. Please note that trained staff will be utilized to match actual volume trends and may need to be adjusted if projected assumptions or actual volumes change.

## CSS Informatics Assumptions

### Hosting Details

The Hosting Costs (Set-up, ASP Support and Maintenance, and Application Support) are based on several factors including the number of applications, number of instances, etc. If any of these increases, then the fees are subject to change.

DESCRIPTION	
	<b>APPLICATION SERVER HARDWARE</b>
Application Servers Hardware and Software	Hardware & Software estimates for Application Server for Oracle AERS – <b>one time pass through costs.*</b> <ul style="list-style-type: none"><li>• <i>AERS Dedicated Application Server - \$8,000</i></li><li>• <i>AERS Dedicated Disaster Recovery Application Server - \$8,000</i></li></ul>
	<b>AERS HOSTING</b>
AERS ASP Set-up	Set-up Activities. <b>(one time cost)</b> <ul style="list-style-type: none"><li>• <i>Install hardware and software</i></li><li>• <i>Validate the environment</i></li><li>• <i>Set up networking connections</i></li><li>• <i>Ensure secure access</i></li></ul> <b>\$53,750</b>
AERS ASP Maintenance	Ongoing maintenance provided during the service period.  <i>Monthly Fee: \$2,625</i>
	<b>APPLICATION SUPPORT</b>
OLS Internal Application Support Package	Application Support Activities for internal Client users for 12 months. Fee for up to four hours/month <ul style="list-style-type: none"><li>• <i>Standard Monthly fee: \$720</i></li><li>• <i>Each additional hour over four hours/month billed at \$175/hour</i></li></ul>

	<b>ORACLE AERS SUBSCRIPTION LICENSES</b>
Oracle AERS Subscription Licenses	Oracle AERS subscription fee is \$340 per user per month with a minimum user base of five users and a minimum subscription timeframe of one year.
	Fee for up to 5 users: <ul style="list-style-type: none"> <li>• Annual fee: \$20,400</li> <li>• Total for 3 years: \$61,200 .</li> <li>• Annual Fee may be deferred over 12 months at a monthly fee of \$1,700.</li> <li>• <u>Additional users may be added for a minimum timeframe of one year</u></li> </ul>
	<b>CLOSEOUT</b>
Service Closeout AERS	Activities associated with concluding ASP use. <b>(one time cost)</b>

- PPD has agreed to allocate the start-up costs related to AERS Set-up and Data Migration over the first 12 months of the project duration, to be paid in full no later than 30 September 2010.
- Our corporate IT typically requires up to a 90 day set-up period after contract execution.
- The fee for ASP Support and Maintenance and for Application Support is payable monthly beginning from the date of Hosting Service Startup and for the duration of the service term. Invoices are due within 30 days of receipt.
- Application Server software maintenance renewal costs are invoiced when incurred.
- Service Closeout, Additional Services and fees for additional Application Support hours are invoiced when these services are provided. Service invoices will list these activities as separate line items

#### Data Migration Details

Migration Tasks	Deliverables	Estimated Total (person-days)
<b>Initial Data Import</b>	<b>Obtain source data</b> <ul style="list-style-type: none"> <li>- Receive source data export from the IRMS system</li> <li>- Import into internal PPD SQL Server database</li> <li>- Import source data into an Oracle database with appropriate data type conversion</li> <li>- Verify table counts; check converted data</li> </ul>	10
<b>Analysis</b>	<b>Mapping requirements specification</b> <ul style="list-style-type: none"> <li>- Screen-level mapping document.</li> <li>- Identify all source fields to be migrated</li> <li>- Map each source screen to one or more target system screens.</li> <li>- Highlight those fields that require transformation.</li> </ul>	15

	<ul style="list-style-type: none"> <li>- Define algorithms to merge, concatenate, truncate, convert, divide and otherwise alter source data as necessary to accommodate the target system configuration</li> <li>- Outline code list matches and discrepancies</li> </ul> <b>Review</b> <ul style="list-style-type: none"> <li>- PPD and/or Graceway review of Mapping Requirements Specification.</li> </ul>	
<b>Development</b>	<b>Migration scripts</b> <ul style="list-style-type: none"> <li>- Create data conversion scripts</li> </ul> <b>Unit test and code review</b> <ul style="list-style-type: none"> <li>- Migrate data to development AERS environment</li> <li>- Evaluate migrated data</li> <li>- Execute Unit tests</li> </ul> <b>Refine migration scripts</b> <ul style="list-style-type: none"> <li>- Update mapping spec as necessary</li> </ul> <b>Detailed mapping specification</b> <ul style="list-style-type: none"> <li>- Document database field mapping</li> </ul>	25
<b>Prototype Migration</b>	<b>Execute subset migration</b> <ul style="list-style-type: none"> <li>- CSSI review of converted data</li> </ul>	5
<b>Review &amp; Evaluate</b>	<b>Review migrated data</b> <ul style="list-style-type: none"> <li>- Feedback from PPD and Graceway review of migrated data</li> </ul>	5
<b>Mapping Finalization</b>	<b>Final migration scripts and mapping documents</b> <ul style="list-style-type: none"> <li>- Refine Mapping Requirements Spec</li> <li>- Update migration source code</li> <li>- Update Detailed Mapping Spec</li> </ul> <b>Execution checklist</b> <ul style="list-style-type: none"> <li>- Generate wrapper scripts and checklists required for production migration</li> </ul>	15
<b>Test Scripts</b>	<b>Migration test scripts</b> <ul style="list-style-type: none"> <li>- Analysis of aggregate counts and distinct value breakdowns for all data items</li> <li>- Checks of selected critical data items (seriousness, death, relatedness, etc.) in 100% of cases</li> <li>- Complete (100%) comparison of case listing data in a selected subset of cases (assumes Graceway will provide case listings for the selected cases from the original IRMS system)</li> </ul>	25
<b>Validation</b>	<b>Validation documents</b> <ul style="list-style-type: none"> <li>- Write Validation plan</li> <li>- Write conversion test plan</li> <li>- Complete required validation documents</li> </ul>	5
<b>Formal Qualification</b>	<b>Migrated data in validation environment</b> <ul style="list-style-type: none"> <li>- Perform functional testing</li> </ul> <b>Functional test results</b>	5

	<ul style="list-style-type: none"> <li>- Migration logs</li> <li>- Test results</li> <li>- Performance metrics</li> </ul>	
<b>Production Migration</b>	<b>Migration complete</b> <ul style="list-style-type: none"> <li>- Completed Migration checklist</li> <li>- Validation documentation</li> <li>- Follow-up support post migration</li> </ul>	<b>5</b>
<b>Project Management</b>	<b>Scheduling, coordination, and communication</b>	<b>10</b>
	<b>ESTIMATED TOTAL</b>	<b>125</b>

## APPENDIX C – BUDGET ESTIMATE

The following budget estimate is based on the assumptions listed in Appendix B and is based on a timeline of 05 October 2009 through 31 December 2012.

<b>Start-up Direct Costs</b>	<b>Unit</b>	<b>No. Units</b>	<b>Cost</b>
Training	Hours	231	\$21,246
IT Implementation	One-Time	1	\$8,178
Oracle Life Science Training (up to 10 trainees for 4 days)	Day	4	\$6,450
<b>TOTAL START-UP DIRECT COSTS</b>			<b>\$35,874</b>
<b>Ongoing Direct Costs</b>	<b>Unit</b>	<b>No. Units</b>	<b>Cost</b>
Project Implementation & SOP Development <sup>1</sup>	Months	12	\$44,648
Program Management	Hours	2,390	\$355,780
IT System Support/Maintenance	Months	36	\$21,600
			<b>\$422,027</b>
<b>Contact Center Operational Support</b>			
Call Handling	Hours	12,480	\$926,622
			<b>\$926,622</b>
<b>Post-Approval PVG Operational Support</b>			
Non-Serious Spontaneous Report Management	Case	2,052	\$314,640
Serious Spontaneous Report Management	Case	108	\$46,116
Simple PSUR (Tier 1)	Report	12	\$7,000
PSUR (Tier 2)	Report	15	\$30,000
Complex PSUR (Tier 3)	Report	3	\$9,800
Literature AE Report Management	Report	72	\$32,856
			<b>\$440,412</b>
<b>CSS Informatics</b>			
Hosting			
AERS Set-up <sup>1</sup>	Months	12	\$53,750
AERS Maintenance	Months	36	\$94,063
Application Support	Months	36	\$25,800
Service Closeout (at conclusion of service)	One-Time	1	\$3,135
Data Migration <sup>1</sup>	Months	12	\$168,750
Subscription Licenses for up to 5 Oracle AERS Users	Years	3	\$61,200
<i>Optional Services (not included in total)</i>			
UAT Packages	One-Time	1	\$7,500
UAT Execution	One-Time	1	\$9,600
			<b>\$406,698</b>
<b>TOTAL ONGOING DIRECT COSTS</b>			<b>\$2,195,759</b>
<b>ESTIMATED TOTAL BUDGET</b>			<b>\$2,231,633</b>
One-Time Program Discount			(\$38,572)
<b>DISCOUNTED ESTIMATED TOTAL BUDGET</b>			<b>\$2,193,061</b>

Note 1: PPD has agreed to allocate the start-up costs related to Project Implementation & SOP Development, AERS Set-up and Data Migration over the first 12 months of the project duration, to be paid in full no later than 30 September 2010. Should this project terminate before 01 October 2010, Graceway will be invoiced and shall pay for the balance owed for these start-up costs incurred by PPD on this program.

Estimated Pass-Through Costs	Price/Unit	Cost
Pass Through Applications Servers and Hardware	\$16,000	\$16,000.00
Internal Document Procurement	\$17.50	As needed
External Document Procurement, Language Translation, Copyright Clearance, Wide Area Network Access, Travel, Supplies, Off-site Storage and Outsourced Copying	\$Cost	As needed
Oracle AERS Access (Per month)	\$425.00	\$15,300.00
Fulfillment (Per Month)	\$191.67	\$6,900.00
Phone (Per month)	\$150.00	\$5,400.00
Miscellaneous	\$100.00	\$3,600.00

PPD invoices on a monthly basis. The services above will be billed at time & materials or per unit according to the fee schedule to be developed in conjunction with the contract upon award.

#### **CSS Informatics Consulting Rates**

Optional consulting services can be provided at the following rates:

Function	Full Daily Rate	Discounted Daily Rate
Validation Consultant	\$1,500	\$1,350
Principal Safety Consultant	\$1,500	\$1,350
Tester or Test Administrator	\$1,500	\$1,200
Standard Training for up to 10 trainees		\$1,612.50, plus \$125/day/additional trainee over 10

All rates are quoted and payable in US Dollars. Client will be billed only for actual hours worked, and no work in excess of the total value of approved Services will be undertaken without a new signed agreement.

- Daily fees are for an eight (8) hour day.
- Minimum billing for on-site consulting is one (1) day (8 hours).
- Hours in excess of eight (8) hours per day will be billed on a prorata basis based on the daily fee.
- Billing for consulting not on Client site will be charged on a prorata basis based on the daily fee.
- Consulting rates shall include incidental office expenses.
- Consulting fees do not include travel. Client will reimburse CSSI for pre-authorized out-of-pocket travel expenses and other reasonable and approved expenses incurred in connection with the Services rendered hereunder, including:
  - Airfare and luggage fees
  - Ground transport
  - Lodging and meals
  - Visas or medical expense incurred for travel outside of the United States.



## APPENDIX D - FEE SCHEDULE

Effective: 05 October 2009 - 31 December 2012

Professional Contact Center		Unit	2009	2010	2011	2012
IT Implementation <sup>1</sup>		One-time	\$5,265.00			
Project Implementation & SOP Development <sup>2</sup>		Per month	\$2,417.50	\$2,417.50		
<b>Ongoing Direct Costs &amp; Training</b>						
Associate Director		Per hour	\$161.00	\$167.25	\$174.00	\$181.00
Operations Supervisor		Per hour	\$121.00	\$126.00	\$131.75	\$137.75
Nurse - Weekday (Mon - Fri)		Per hour	\$68.50	\$71.25	\$74.25	\$77.25
Nurse - Crisis & Holiday **		Per hour	\$101.75	\$105.75	\$110.00	\$114.50
IT System Support / Maintenance <sup>3</sup>		Per month		\$400.00	\$400.00	\$400.00
<b>Product Safety &amp; Pharmacovigilance</b>						
IT Implementation <sup>1</sup>		One-time	\$2,913.00			
Project Implementation & SOP Development <sup>2</sup>		Per month	\$1,303.00	\$1,303.00		
<b>Ongoing Direct Costs</b>						
Program Management <sup>4</sup>		Per month		\$3,687.00	\$3,850.00	\$4,024.00
IT System Support / Maintenance <sup>3</sup>		Per month		\$200.00	\$200.00	\$200.00
Non-Serious Spontaneous Report Management		Per case		\$147.00	\$153.00	\$160.00
Serious Spontaneous Report Management		Per case		\$408.00	\$427.00	\$446.00
Literature AE Report Management		Per report		\$436.00	\$456.00	\$477.00
<b>Additional Hourly Support, as required (including Training &amp; Aggregate Report preparation)</b>						
Medical Director		Per hour	\$249.75	\$259.00	\$269.50	\$280.50
Director		Per hour	\$208.00	\$215.75	\$224.50	\$233.50
Associate Director		Per hour	\$165.50	\$171.75	\$178.75	\$186.00
Manager		Per hour	\$143.75	\$150.00	\$156.75	\$164.00
Safety Specialist		Per hour	\$114.00	\$118.75	\$124.25	\$130.00
Safety Administrator		Per hour	\$68.25	\$71.00	\$74.00	\$77.00

[Please see footnote details on next page.]

CSS Informatics		Unit		2009	2010	2011	2012
Oracle Life Science Training (up to 10 trainees for 4 days) <sup>1</sup>		One-time		\$6,450.00			
AERS Set-up <sup>2</sup>		Per month		\$4,479.17	\$4,479.17		
Data Migration <sup>2</sup>		Per month		\$14,062.50	\$14,062.50		
Subscription Licenses for up to 5 Oracle AERS Users <sup>3</sup>		Per Month			\$1,700.00	\$1,700.00	\$1,700.00
AERS Maintenance <sup>3</sup>		Per month			\$2,625.00	\$2,625.00	\$2,625.00
Application Support <sup>3,5</sup>		Per month			\$720.00	\$720.00	\$720.00
Service Closeout (at conclusion of service)		One-time			\$3,135.00		
UAT Packages (optional service)		One-time			\$7,500.00		
UAT Execution (optional service)		One-time			\$9,600.00		

Pass-Through Costs		Unit		Rate
External Document Procurement, Language Translation, Copyright Clearance, Phone and Fax Usage, Postage & In-house Fulfillment, Wide Area Network Access, Travel, Supplies, Off-site Storage and Outsourced Copying			As needed	\$Cost
Internal Document Procurement			Per document	\$17.50
Oracle AERS Access (January 2010 – December 2012)			Per month	\$425.00
Fee for providing the use of dedicated AERS application server and software			One-time	\$8,000.00
Fee for providing the use of dedicated AERS disaster recovery server and software			One-time	\$8,000.00

PPD invoices on a monthly basis according to the rates shown in this fee schedule. Additional billing details are described in the following notes.

Note 1: The one-time IT Implementation costs will be billed as a lump sum cost immediately upon execution of the contract or letter of intent as these activities will begin immediately. The one-time Oracle Life Science Training cost will be billed immediately upon completion of the training.

Note 2: PPD has agreed to allocate the start-up costs related to Project Implementation & SOP Development, AERS Set-up and Data Migration over the first 12 months of the project duration. These costs will therefore be billed at the indicated monthly rates for each activity beginning October 2009 through September 2010. Should this project terminate before October 2010, Graceway will be invoiced and shall pay for the balance owed for these start-up costs incurred by PPD.

Note 3: These costs will be invoiced at the indicated monthly rate for each activity beginning January 2010 through December 2012.

Note 4: Post-Approval PVG program management will be billed at the monthly rate shown for each year. Should program management exceed 24 hours per month, it will be billed at actual hours according to the hourly rates associated with the staff performing the tasks.

Note 5: Application support in excess of four hours per month will be billed at \$175 per hour.

### **One-time Program Discount**

There is a maximum total discount of (\$38,572) that pertains to the Post-Approval PVG services provided under this Agreement. This discount equates to 6% of the estimated Post-Approval PVG budget and applies only to direct costs. It will be included on each monthly invoice containing Post-Approval PVG services until the total maximum discount of (\$38,572) is achieved within the duration of this project. No further discounting will apply once the total discount amount is achieved. If the Post-Approval PVG services are terminated prior to achieving the total discount, any discount balance remaining will be forfeited.

\*\* The following days are considered as holidays for the purpose of this Agreement. If requested in writing at least 60 working days in advance, the PCC will provide services on these days as mutually agreed at the listed holiday rates.

New Year's Day (observed)  
Good Friday  
Memorial Day  
July Fourth (observed)  
Labor Day  
Thanksgiving  
Day After Thanksgiving  
Christmas Day (observed)  
Day After Christmas or Christmas Eve Day (observed)

Should the project operate on weekends, holiday rates will apply to Easter Sunday and to weekend days on which the above-observed holidays actually occur.

**ORIGINAL**

**AMENDMENT 1 TO  
SERVICES AGREEMENT**

This Amendment 1 ("Amendment 1") is made by and between ATP, LLC d/b/a PPD Medical Communications ("PPD") and Graceway Pharmaceuticals ("CLIENT") and shall be effective as of March 1, 2010.

WHEREAS, the parties entered into a Services Agreement dated December 21, 2009 (the "Agreement"); and

WHEREAS, the parties wish to amend the Agreement to accommodate PPD's provision of additional services as requested by CLIENT.

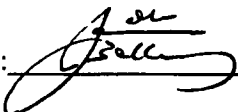
NOW, THEREFORE, in consideration of the mutual covenants set forth in this Amendment 1, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. PPD shall perform Data Migration Services ("DM Services") for an additional period of 33 days to be completed by 16 March 2010. The fee for said DM Services shall be \$1,215 per day (reflecting a discount from the standard rate of \$1,350 per day), resulting in a total fee for the additional DM Services of \$40,095.
2. PPD has agreed to allocate the total fee for the additional DM Services over months 13 to 15 of the project duration. For clarity, PPD shall invoice and CLIENT shall pay \$13,365 each month for October, November and December of 2010 for the additional DM Services.
3. Capitalized terms used herein and not otherwise defined herein shall have the meaning ascribed to them in the Agreement.
4. In the event of any inconsistency or conflict of terms between the Agreement and this Amendment 1, the terms of this Amendment 1 shall control.
5. Except as provided herein, all other terms and conditions of the Agreement shall remain in full force and effect.

[Next Page is Signature Page]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment 1 to be executed as of the date first above written.

GRACEWAY PHARMACEUTICALS, LLC

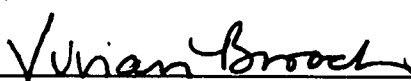
By: 

Name: John Bellamy

Title: EVP + GC

Date: 14 May 2010

ATP, LLC

By: 

Name: Vivian Broach

Title: VP, Operations

Date: 19 May 2010



**AMENDMENT 2 TO  
SERVICES AGREEMENT**

**THIS AMENDMENT NO. 2** ("Amendment 2") is made by and between ATP, LLC d/b/a PPD Medical Communications ("PPD") and Graceway Pharmaceuticals ("CLIENT") and shall be effective as of September 27, 2010.

**WHEREAS**, the parties entered into a Services Agreement dated December 21, 2009 as amended by Amendment No. 1 dated March 1, 2010 (collectively, the "Agreement"); and

**WHEREAS**, the parties wish to further amend the Agreement as set forth herein.

**NOW, THEREFORE**, in consideration of the mutual covenants set forth in this Amendment 2, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. All references to "CSS Informatics" or "CSSI" shall be deleted and replaced with "Safety Technical Operations" and "STO" respectively.
2. PPD shall perform Oracle Life Science Training on CLIENT site to be completed by April 25, 2011. The fee for said training is detailed in Appendix D – Fee Schedule. The training fee does not include travel costs; relevant travel costs will be billed in addition at cost as a pass-through expense on the monthly invoice to CLIENT.
3. Appendix D – Fee Schedule shall be deleted in its entirety and replaced with the revised Appendix D attached hereto.
4. Section 2.5 shall be deleted in its entirety and replaced with the following:

"All payments to PPD under this Agreement shall be made as follows:

If by check, payment mailed to:      ATP, LLC d/b/a PPD Medical Communications  
12937 Collections Center Drive  
Chicago, IL 60693  
Tax ID # 74-2325267

If electronically, payment sent to:      Bank of America  
Account #: 000696217456  
ABA: 026009593 (WIRE)  
ABA: 053000196 (ACH)  
Account Name: PPD Development, LP"

5. Capitalized terms used herein and not otherwise defined herein shall have the meaning ascribed to them in the Agreement.
6. In the event of any inconsistency or conflict of terms between the Agreement and this Amendment 2, the terms of this Amendment 2 shall control.
7. Except as provided herein, all other terms and conditions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment 2 to be executed as of the date first above written.

GRACEWAY PHARMACEUTICALS, LLC

By: Sean Brennan

Name: \_\_\_\_\_

Title: Sr VP

Date: 15 APR 2011

ATP, LLC

By: Vivian Broach

Name: Vivian Broach

Title: VP, Operations

Date: 26 Apr 2011



**AMENDMENT 2 TO  
SERVICES AGREEMENT**

**APPENDIX D – FEE SCHEDULE**

Effective: 01 April 2011 – 31 December 2012

Professional Contact Center	Unit	2011	2012
Associate Director	Per hour	\$174.00	\$181.00
Operations Supervisor	Per hour	\$131.75	\$137.75
Nurse – Weekday (Mon – Fri)	Per hour	\$74.25	\$77.25
Nurse – Crisis & Holiday **	Per hour	\$110.00	\$114.50
IT System Support / Maintenance <sup>1</sup>	Per month	\$400.00	\$400.00
Product Safety & Pharmacovigilance	Unit	2011	2012
Program Management <sup>2</sup>	Per month	\$3,850.00	\$4,024.00
IT System Support / Maintenance <sup>1</sup>	Per month	\$200.00	\$200.00
Non-Serious Spontaneous Report Management	Per case	\$153.00	\$160.00
Serious Spontaneous Report Management	Per case	\$427.00	\$446.00
Literature AE Report Management	Per report	\$456.00	\$477.00
<b><i>Additional Hourly Support, as required (including Training &amp; Aggregate Report preparation)</i></b>			
Medical Director	Per hour	\$269.50	\$280.50
Director	Per hour	\$224.50	\$233.50
Associate Director	Per hour	\$178.75	\$186.00
Manager	Per hour	\$156.75	\$164.00
Safety Specialist	Per hour	\$124.25	\$130.00
Safety Administrator	Per hour	\$74.00	\$77.00
Safety Technical Operations	Unit	2011	2012
Oracle Life Science Training (up to 10 trainees for 1 day) <sup>1</sup>	One-time	\$1,800.00	
Subscription Licenses for up to 5 Oracle AERS Users <sup>3</sup>	Per Month	\$1,700.00	\$1,700.00
AERS Maintenance <sup>1</sup>	Per month	\$2,625.00	\$2,625.00
Application Support <sup>1,3</sup>	Per month	\$720.00	\$720.00
Service Closeout (at conclusion of service)	One-time	\$3,135.00	
UAT Packages (optional service)	One-time	\$7,500.00	
UAT Execution (optional service)	One-time	\$9,600.00	

Note 1: These costs will be invoiced at the indicated monthly rate for each activity beginning April 2011 through December 2012.

Note 2: Post-Approval PVG program management will be billed at the monthly rate shown for each year. Should program management exceed 24 hours per month, it will be billed at actual hours according to the hourly rates associated with the staff performing the tasks.

Note 3: Application support in excess of four hours per month will be billed at \$175 per hour.



Pass-Through Costs	Unit	Rate
External Document Procurement, Language Translation, Copyright Clearance, Phone and Fax Usage, Postage & In-house Fulfillment, Wide Area Network Access, Travel, Supplies, Off-site Storage and Outsourced Copying	As needed	\$Cost
Internal Document Procurement	Per document	\$17.50
Oracle AERS Access (April 2011 – December 2012)	Per month	\$425.00
Fee for providing the use of dedicated AERS application server	One-time	\$8,000.00
Fee for providing the use of dedicated AERS disaster recovery	One-time	\$8,000.00

PPD invoices on a monthly basis according to the rates shown in this fee schedule.

#### **One-time Program Discount**

There is a maximum total discount of (\$38,572) that pertains to the Post-Approval PVG services provided under this Agreement. This discount equates to 6% of the estimated Post-Approval PVG budget and applies only to direct costs. It will be included on each monthly invoice containing Post-Approval PVG services until the total maximum discount of (\$38,572) is achieved within the duration of this project. No further discounting will apply once the total discount amount is achieved. If the Post-Approval PVG services are terminated prior to achieving the total discount, any discount balance remaining will be forfeited.

**\*\*** The following days are considered as holidays for the purpose of this Agreement. If requested in writing at least 60 working days in advance, the PCC will provide services on these days as mutually agreed at the listed holiday rates.

New Year's Day (observed)  
 Good Friday  
 Memorial Day  
 July Fourth (observed)  
 Labor Day  
 Thanksgiving  
 Day After Thanksgiving  
 Christmas Day (observed)  
 Day After Christmas or Christmas Eve Day (observed)

Should the project operate on weekends, holiday rates will apply to Easter Sunday and to weekend days on which the above-observed holidays actually occur.



FILED

2011 DEC -6 PM 12:59

VIA UPS

December 2, 2011

CLERK  
US BANKRUPTCY COURT  
DISTRICT OF DELAWARE

United States Bankruptcy Court  
District of Delaware  
Attn: Clerks Office  
824 Market St., 3rd Floor  
Wilmington, DE 19801

**Re: Proof of Claim for ATP, LLC- PPD Medical Communications**

To Whom it May Concern:

Enclosed, please find the completed Proof of Claim form for ATP, LLC. The Case # is 11-13036.

Sincerely,

Sandy Reeves  
Executive Assistant

Encls. (1)