

## Instructions for subscribing to the UW Drug Interaction Database UW CoMotion

The UW Drug Interaction Database (referred as DIDB), part of UW Drug Interaction Solutions, features the largest collection of pharmacokinetic-based drug interaction data and includes the following datasets:

- Preclinical (*in vitro*, human) Drug Metabolism
- Preclinical (*in vitro*, human) Drug Transporter
- Clinical Drug Interaction
- Clinical Organ Impairment
- Clinical Pharmacogenetics

The DIDB is made available as part of the University of Washington Express Licensing program. You will find the license fee structure for the DIDB identified in Schedule B of the attached subscription agreement.

1. To license the DIDB, please read carefully the agreement and schedules and do the following:
  - a) Print the subscription agreement (an as-is agreement), including all schedules
  - b) Complete your **organization's details** at the top of the first page
  - c) Complete the **Administrative Contact** information in the "Definitions" Section
  - d) Complete the **Access Type and License Fee table** (based on your company size and access type desired), the **proposed use** (if applicable) and the **Scientific Contact** information in Schedule B
  - e) Have the license agreement signed by an authorized representative
  - f) Return the completed and partially executed agreement to [license@uw.edu](mailto:license@uw.edu) or fax to (206) 616-3322. You may also send a Purchase Order (if desired) at this time. For purchasing questions, please contact Express Licensing Program at (206) 543-3970 or [license@uw.edu](mailto:license@uw.edu).
2. UW will review the license agreement, and if everything is in order, you will receive a copy of the executed agreement and an invoice. The invoice will include a license agreement number.
3. Please make check payable to: University of Washington. Please indicate the license number and invoice number on your check. Please mail the check to:  
ATTN: Express Licensing Program  
UW CoMotion  
University of Washington  
4545 Roosevelt Way NE, Suite 400  
Seattle, WA 98105  
Wire transfer is also available, subject to a \$30 fee. You must follow the instructions on the invoice in order to pay with a wire transfer.
4. Access to the DIDB will begin after UW executes and sends the agreement to you. The date that UW provides access to the DIDB to you will be the starting date of your year of access to the DIDB.

You may contact our office if you have any questions about this process:

Express Licensing Program  
UW CoMotion Innovation Development  
Phone: (206) 543-3970 ; Fax: (206) 616-3322  
Email: [license@uw.edu](mailto:license@uw.edu)

For technical information on the DIDB, please contact [didbase@uw.edu](mailto:didbase@uw.edu).

**UW Drug Interaction Database  
Subscription Agreement**

The University of Washington, a public institution of higher education having administrative offices at 4545 Roosevelt Way NE, Suite 400 Seattle, Washington 98105 (“UW”) and \_\_\_\_\_  
\_\_\_\_\_, with its administrative offices at \_\_\_\_\_  
\_\_\_\_\_ (“Subscriber”) agree as follows, effective as of the latest date upon which this Agreement is fully executed (“Effective Date”):

**Background** UW desires to make available the Work (as defined below), developed in UW’s Department of Pharmaceutics, Drug Interaction Solutions Team, School of Pharmacy, under the direction of Professor Isabelle Ragueneau-Majlessi.

Subscriber is an organization involved in the development of pharmaceutical drugs and/or provision of contract research, consulting, or other therapeutics development-related services, and desires access to the Work for Authorized Users.

**Definitions** “Affiliate” means any organization or business entity directly or indirectly controlling, controlled by or under common control with Subscriber, that (a) agrees to be bound by all terms and conditions of this Agreement to the same extent as Subscriber (except for paying the License Fee), and (b) whose acts and omissions are Subscriber’s responsibilities. For purposes of this definition only, “control” of another organization or business entity means the ability, directly or indirectly, to direct the activities of the relevant entity, and includes, without limitation (i) ownership or direct control of fifty percent (50%) or more of the outstanding voting stock or other ownership interest of the other organization or business entity, or (ii) possession of, or the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the other organization or business entity.

“Agreement” means this Subscription Agreement, with the attached Schedules.

“Authorized User” means (a) current employees and interns of the Subscriber, and (b) current consultants and contractors of the Subscriber, whose conduct is subject to reasonable regulation by the Subscriber, and whose acts and omissions are the responsibility of Subscriber; provided, however, that (i) in each of cases (a) and (b) the relevant individuals are permitted by the Subscriber to access the Work from within or outside Subscriber’s premises, have been notified of the terms and conditions of this Agreement, including without limitation the Disclaimers Section, have been given a password by Subscriber, and are accessing the Work only for the purpose of conducting work for the Subscriber; and (ii) any rights granted under this Agreement to consultants and contractors are solely for Subscriber’s projects and benefit, on an as-needed basis only, and shall otherwise be revoked.

“Administrative Contact” means an individual who is authorized by Subscriber to receive notices and communications from UW of an administrative nature. The Administrative Contact is:

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

Title: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

“**Delivery Date**” means the date that UW provides access to the Work to Subscriber. The Delivery Date shall occur within five (5) business days of Effective Date.

“**Global**” means access level to the Work by Subscriber that encompasses all of Subscriber’s locations, and which is provided subject to payment by Subscriber of the relevant License Fee as set forth on Schedule B.

“**License Fee**” means the amount due for the permissions herein from Subscriber under this Agreement as set forth on Schedule B.

“**Scientific Contact**” means an individual who is authorized by Subscriber to receive notices and communications from UW of a scientific nature.

“**Site**” means a single street address, building, single campus, or other single geographic location of Subscriber where Authorized Users are usually located. Sites authorized to access the Work are listed on Schedule B.

“**UW Administrative Contact**” means the UW point of contact for receiving notices and communications from Subscriber of an administrative nature. The UW Administrative Contact is:

UW CoMotion Innovation Development  
Express Licensing Program  
Phone: (206) 543-3970  
Fax: (206) 616-3322  
Emails: [license@uw.edu](mailto:license@uw.edu), copying: [didbase@uw.edu](mailto:didbase@uw.edu) and [ipfin@uw.edu](mailto:ipfin@uw.edu)  
Full address: UW CoMotion  
University of Washington  
4545 Roosevelt Way NE, Suite 400  
Seattle, WA 98105  
United States of America

“**Work**” means the Drug Interaction Database (DIDB), as specified in Schedule A.

## **Permission**

Commencing on the Effective Date and subject to Subscriber complying with the terms of this Agreement, UW hereby grants to Subscriber, and Subscriber hereby accepts, a limited, non-transferable, non-exclusive license to perform the following through Subscriber’s Authorized Users.

If this subscription is Global (as indicated by the Access Type and License Fee table in Schedule B), Subscriber may extend rights granted to Subscriber under this Agreement to Affiliates.

Subscriber may query, view, retrieve, and display the Work. Subscriber may download, export, and print individual items from the Work which may be stored, analyzed, and distributed internally.

Subscriber may provide individual items from the Work in communications with regulatory authorities in connection with the Subscriber's products and services.

Subscriber may provide individual items from the Work to individual third parties upon request or on an ad-hoc basis, in each case for scientific information purposes that directly relate to Subscriber products and services, and for Subscriber's benefit, provided that: (a) the foregoing explicitly excludes any commercial or clinical care use, and (b) any copies supplied must carry without modification copyright notices or other notices related to intellectual property already incorporated in the Work.

Subscriber may quote limited extracts from the Work for research publication only, not for commercial use or sale, and following the citation instructions set out in this Agreement.

Subscriber may access the Work for purposes of planning and conducting clinical trials in compliance with the laws and regulations of the relevant jurisdiction, subject to the terms and conditions of this Agreement, and provided that Subscriber grants access to Work or output from the Work solely to individuals who are researchers knowledgeable in drug interactions and who have been notified of the terms and conditions of this Agreement including without limitation the Disclaimers Section. Subscriber understands and warrants that access to the Work for such purposes is not intended to be, nor will it be used as, a substitute for the knowledge, expertise, skill, and judgment, of any qualified personnel and licensed healthcare professionals as required in the relevant jurisdiction.

In the case of Authorized Users who access the Work using Subscriber's organizational log in (registration information) and whose email address domain is not the same as the one substantially used by employees of Subscriber, the UW will first confirm with Subscriber such individuals' status prior to granting them access rights under this Agreement. Each Authorized User must access and use no more than one distinct Work account not to be shared with other Authorized Users, and Subscriber will timely notify the UW in case such individual ceases to be an Authorized User for any reason, in which case the UW will proceed to deactivate such account. For clarity, the UW may contact Subscriber from time to time with a list of individual Authorized User accounts, in order to confirm such accounts are still active, and Subscriber will respond in a timely fashion.

## **Conditions**

The Work is the intellectual property of the University of Washington, and Subscriber acquires no proprietary interest in the Work.

Any rights granted to Subscriber under this agreement are subject to the following: (a) any download, storing, and distribution of the Work is limited to non-substantial portions of the Work; (b) internal use of the Work is limited to Authorized Users, unless otherwise explicitly indicated; (c) any access to the Work is subject to the access level designated in Schedule B; and (d) any access to the Work is for internal purposes, unless otherwise explicitly indicated.

Subscriber shall not remove or obscure rights management markings, such as copyright notices and patent numbers, from the Work or printouts from the Work.

Subscriber agrees not to download, retain, or reproduce substantial portions of the Work, whether by automated polling systems, manual execution of sequential queries, or any other means, other than downloads explicitly provided by UW as part of the normal features of the Work. Subscriber may access or download non-substantial portions of the Work using automated systems, subject to prior written approval by the UW.

Subscriber shall notify in writing each Authorized User of the disclaimers provided in Agreement regarding information contained in the Work and restrictions for purpose of access to the Work.

Subscriber agrees to acknowledge that the Work is the intellectual property of the University of Washington and Copyright in the Work shall be cited in all output from the Work and/or in any reference to the output from the Work as follows: “Copyright University of Washington. UW Drug Interaction Database, accessed on: ... *[Fill in date of extraction of the data/information].*”

Any use of the Work by Subscriber in publications shall include a citation to the DIDB as a footnote and/or in the reference or acknowledgment section as follows: “This information is based on or an extract from the UW Drug Interaction Database (DIDB), Copyright University of Washington, accessed on: ... *[Fill in appropriate date information].*”

Subscriber acknowledges that Work is for informational and educational purposes only and is not a substitute for the professional judgment of Subscriber.  
SUBSCRIBER’S RELIANCE UPON WORK IS SOLELY AT SUBSCRIBER’S OWN RISK.

Subscriber shall not sublicense, sell, rent, lend, or lease any of the Work. Other than as expressly allowed under this Agreement, Subscriber shall not display or otherwise transfer all or any of the Work.

Subscriber shall promptly notify UW of Subscriber’s involvement in any merger or acquisition as allowed by law; such activity may impact Licensee Fee.

Subscriber shall not access the Work or provide information from the Work for any patient treatment, provided that access for planning and conducting clinical trials is permitted solely as described in the Permission Section.

Subscriber shall request and implement a new password to the Work as necessary, such as termination of an Authorized User.

## **Subscription**

For one (1) year from Delivery Date, UW shall endeavor to correct program defects as identified by UW relating to Work’s operation, to provide periodic updates to the content of Work as these are prepared by the UW Drug Interaction Solutions team, and to provide to Subscriber instructions in response to inquiries made in the form of electronic mail to UW at the following address: [didbase@uw.edu](mailto:didbase@uw.edu).

Any such efforts by UW, however, shall be on an as-available basis and UW’s efforts in responding to inquiries are limited to a total of five (5) hours each term Subscriber licenses the Work.

UW may contact Subscriber to request feedback on use of Work to assist in development of Work at mutually convenient times, up to a limit of five (5) hours per each term Subscriber licenses the Work, unless Subscriber authorizes additional time.

**Delivery** UW shall provide Subscriber access to Work by means of password and internet address for Work. Subscriber authorizes that delivery is to be made to the Scientific Contact.

**Payment** Subscriber shall pay to UW a License Fee as set forth on Schedule B, due upon execution of this Agreement. Should payment not be received from Subscriber by UW within sixty (60) days of Effective Date, UW, at its sole discretion, may terminate this Agreement without notice.

**Term** This Agreement shall expire one (1) year from Delivery Date, and may be renewed annually, provided UW sends Subscriber an invoice for one (1) year of service, and Subscriber's timely payment of the License Fee is received by UW. The License Fee applicable for such renewal shall be based on Subscriber's category upon renewal under the Access Type and License Fee table in Schedule B, and shall include a 1% annual increase.

**Termination** Provided Subscriber has paid License Fee, Subscriber may terminate this Agreement at any time upon thirty (30) days written notice to UW. UW shall not refund to Subscriber any portion of License Fee received by UW for early termination.

UW may terminate this Agreement upon notice if Subscriber is in breach of this Agreement and fails within thirty (30) days of a written demand for performance to cure such breach. After such notice period elapses, access to Work will be immediately terminated. Notwithstanding the foregoing, the UW may terminate this Agreement and terminate access to the Work in case of nonpayment of the License Fee in full where such nonpayment has not been cured by Subscriber within seven (7) days after the UW has provided notice of the same.

The provisions under which this Agreement may be terminated shall be in addition to any and all other legal remedies which either party may have for the enforcement of any and all terms hereof, and do not in any way limit any other legal remedy such party may have.

Termination of this Agreement shall terminate all rights and permissions granted to Subscriber relating to the Work. The obligation to pay any required License Fee survives termination of this Agreement. For clarity, upon termination Subscriber may retain data from the Work if the relevant License Fee was paid and the data was derived in compliance with the terms and conditions of this Agreement.

**Disclaimers** The Work has been developed as part of research conducted at the University of Washington. The Work is experimental in nature and is made available "AS IS", without obligation by UW to provide accompanying services or support except as specified in this Agreement. The entire risk as to the quality and performance of the Work is with Subscriber.

Subscriber acknowledges that the intended audience for the Work is researchers knowledgeable in drug interactions. Subscriber acknowledges that the Work is solely a selected compilation of publicly available literature, and UW makes no warranty on the accuracy, validity, completeness or availability of information cited in the Work. The information contained in the Work is intended as a supplement to, and not a substitute for, the knowledge, expertise, skill and judgment of Authorized Users. The absence of a warning for a given drug or drug combination should not be construed to indicate that the drug or drug combination is safe, appropriate or effective in any given patient.

UW is an agency of the state of Washington and is subject to the Washington Public Records Act, RCW 42.56 et seq., (“Act”), and no obligation assumed by UW under this Agreement will be deemed to be inconsistent with UW’s obligations as defined under the Act and as interpreted by UW in its sole discretion. If UW receives a request for public records under the Act for documents containing Subscriber confidential information, and if UW concludes that the documents are not otherwise exempt from public disclosure, UW will provide Subscriber notice of the request before releasing such documents. Such notice will be provided in a timely manner to afford Subscriber sufficient time to review such documents and/or seek a protective order, at Subscriber’s expense utilizing the procedures described in RCW 42.56.540. UW will have no other obligation to protect Subscriber confidential information from disclosure in response to a request for public records.

UW EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, PERTAINING TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF WORK OR ANY SUBJECT MATTER OTHERWISE PROVIDED TO SUBSCRIBER UNDER THIS AGREEMENT.

**Release and Indemnification**

Subscriber hereby releases UW and its regents, employees, and agents forever from any and all suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys’ and investigative expenses) relating to or arising out of Subscriber’s possession and/or use of the Work. To the extent allowed by law, Subscriber shall indemnify and hold harmless UW, and its officers, Work developers, employees, students, and agents, against any and all claims, suits, losses, damages, costs, fees, and expenses resulting from Subscriber’s possession and/or use of Work, including but not limited to any damages, losses, or liabilities whatsoever with respect to death or injury to any person and damage to any property. This release and indemnification clause shall survive the termination of this Agreement.

**No Known Infringement**

As of the Effective Date, to the best of UW’s CoMotion office’s knowledge, (a) no claim has been made or is threatened charging UW with infringement of, or claiming that the Work infringes any third party rights; and (b) no proceedings have been instituted, or are pending or threatened, which challenge the UW’s rights in respect to the Work.

**General**

This Agreement shall be construed in accordance with, and its performance shall be governed by, the laws of the State of Washington, United States. Any suit, action, or proceeding arising out of or relating to this Agreement shall be decided in King County, Washington, U.S.A. Subscriber accepts the venue and jurisdiction of the Federal District Court of Western Washington, Seattle, or the King County Superior

Courts. The application of the United Nations Convention for contracts for the International Sales of Goods is hereby expressly excluded.

Any notice required to be given to a party shall be addressed to the address of that party provided herein, by a recognized overnight courier service (e.g. Federal Express, DHL). If an email address(es) is/are included for the Administrative Contact and/or the UW Administrative Contact, then transmission of an email to such email address(es) will constitute valid notice under this Agreement provided such delivery is confirmed (not by means of an automated email response). Notices and communications relating to this Agreement will be deemed to have been given when received.

No omission or delay of either party hereto in requiring due and punctual fulfillment of the obligations of any other party hereto shall be deemed to constitute a waiver by such party of its rights to require such due and punctual fulfillment, or of any other of its remedies hereunder. Amendments to this Agreement must be in writing, reference this Agreement, and be signed by duly authorized representatives of UW and Subscriber. Headings are provided for convenience only.

If any provision of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not be in any way affected or impaired thereby.

This Agreement and the rights and benefits conferred upon Subscriber hereunder may not be assigned or otherwise transferred by Subscriber without the prior written consent of UW. This Agreement may be assigned by UW.

Failure of UW to perform or delay in the performance of UW's obligations under this Agreement due to any cause or event not reasonably within UW's control, including but not limited to casualty, labor disputes, failure of equipment, compliance with government authority or Act of God, shall not constitute a breach of this Agreement, and UW's performance shall be excused during such delay.

This Agreement embodies the entire understanding of the parties and supersedes all previous communications, representations, or understandings, either oral or written, between the parties relating to the subject matter hereof.

UW and Subscriber have executed this Agreement by their respective duly authorized representatives on the dates given below.

**Subscriber**

**University of Washington**

By: \_\_\_\_\_

By: \_\_\_\_\_

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

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

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

## Schedule A

### The Work

The Drug Interaction Database (referred to as DIDB), within Drug Interaction Solutions, is designed to support scientists and clinicians in their decision-making when evaluating PK-based drug interactions and drug safety.

The database has a large manually curated collection of qualitative and quantitative human *in vitro* and *in vivo* information related to various extrinsic and intrinsic factors. These factors include interacting co-medications, excipients, food products, herbals, tobacco, organ impairment, and genetics that can affect drug exposure in humans.

The information on drug disposition available in the database includes:

- *In vitro* drug metabolism, drug transport and drug-drug interactions (DDIs) (involving human metabolizing enzymes, human transporters, and their variants)
- Clinical DDIs and case reports
- Clinical pharmacogenetics
- Other DDI mechanisms including clinical absorption-based interactions (e.g., food effect, pH-dependence, etc.)
- Clinical hepatic and renal impairment

The DIDB includes specific data and results from peer-reviewed journal articles referenced in Medline, Embase, reference textbooks, guideline documents, FDA Drug Labels, and NDA/BLA Reviews. Both *in vitro* and *in vivo* drug interaction studies are included in the database, making it useful to both pre-clinical and clinical scientists. PK profiles of drugs, QT Prolongation data, as well as Regulatory Guidances and Editorial Summaries/Syntheses can also be found.

All curation activities and editorial tasks are performed in-house by the UW Drug Interaction Solutions team that is dedicated to the database and user support.

The UW Drug Interaction Solutions team is formed of research scientists with PhD, PharmD, or MD degrees who select, analyze, and add data routinely to the database.

Users can search the DIDB using a large number of queries and approach the data from many different perspectives.

**Schedule B  
License Fee and Contact Information**

Select the appropriate access level and license fee below by filling in where indicated. Indicate total License Fee to the right. Fees are valid for one (1) year of access.

<b>Access Type and License Fee*</b>						
5000 or more employees	<b>Site-based Access:</b>				\$	
	1 Site	2 Sites	3 Sites	4 Sites or more/ Global		
	\$23,385	\$35,076	\$46,768	\$58,460		
2500 - 4999 employees	<i>Note:</i> For a single organization's use.			\$11,692	\$	Total:  \$
1001-2499 employees	<i>Note:</i> For a single organization's use.			\$8,769	\$	
501- 1000 employees	<i>Note:</i> For a single organization's use.			\$5,847	\$	
101- 500 employees	<i>Note:</i> For a single organization's use.			\$4,093	\$	
1-100 employees	<i>Note:</i> For a single organization's use.			\$2,923	\$	

\*Subject to a 1% annual increase upon renewal

**Payment Information**

With each payment, Subscriber shall indicate the number of Sites for which Work is licensed and the appropriate License Fee calculation.

Payment shall be made in U.S. dollars by check or money order to University of Washington:

ATTN: Express Licensing Program  
 UW CoMotion Innovation Development  
 University of Washington  
 4545 Roosevelt Way NE, Suite 400  
 Seattle, WA 98105

Remember to indicate the license number and invoice number on your check. Wire transfer is also available subject to an additional \$30 fee to be added to the payment. Subscriber shall be responsible for any charges, taxes and/or customs duties associated with payments made under this Agreement.

**Description of Proposed Use (for service providers only)**

If Subscriber provides contract research, consulting, or other services related to therapeutics development, for which access to the Work is used, please briefly describe your activities:

**Organization Information for Subscriber:**

Please fill out part A **OR** part B below, as instructed:

A. If the subscription **is not** a Site-based license:

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

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

**Scientific Contact:**

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

Title: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

Fax (if applicable): \_\_\_\_\_

B. If the subscription **is** a Site-based license:

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

**Scientific Contact:**

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

Title: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

Fax (if applicable): \_\_\_\_\_

**Site #1**

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

Full Address: \_\_\_\_\_

\_\_\_\_\_

**Site #2**

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

Full Address: \_\_\_\_\_

\_\_\_\_\_

**Site #3**

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

Full Address: \_\_\_\_\_

\_\_\_\_\_