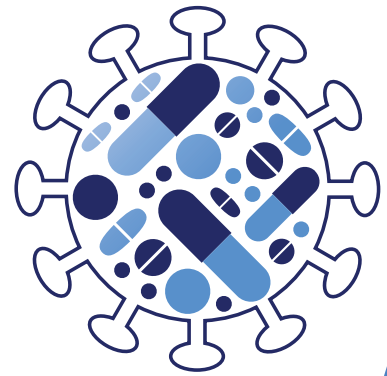


# INTERNATIONAL WORKSHOP ON CLINICAL PHARMACOLOGY 2023

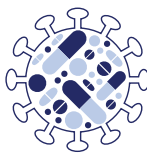
OF HIV,  
HEPATITIS  
AND OTHER  
ANTIVIRAL  
DRUGS



**HYBRID WORKSHOP**  
11 - 13 SEPTEMBER 2023  
ROME, ITALY

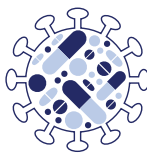
## Program Book





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Dear Colleague,

We are delighted to welcome you to the 24th edition of the **International Workshop on Clinical Pharmacology of HIV, Hepatitis, and Other Antiviral Drugs**, and the second hybrid edition. Building on the success of the 2022 hybrid meeting in Barcelona, we are thrilled to host this meeting live in Rome, Italy, and include virtual attendees all over the world.

Understanding the clinical pharmacology of antiviral therapy is pivotal to designing optimal treatment and prevention strategies for HIV, hepatitis, COVID-19 and other viral illnesses.

This edition of the **International Workshop on Clinical Pharmacology of HIV, Hepatitis, and Other Antiviral Drugs** gathers leading experts to discuss aspects impacting the optimal use of antiviral therapy for both old and new infections. The program covers a wide range of topics, including drug-drug interactions, pharmacokinetics of investigational and existing drugs, pharmacodynamics, drug dosing in key populations, and regulatory considerations.

In addition to invited lectures by international leading experts, the core of the program is structured around oral and poster abstract presentations, often by Early-Career Investigators. The relatively small size and structure of the workshop facilitates personal interactions among attendees and speakers both in person and virtually. In addition to abstract presentations, the debate and roundtable will allow for opportunities for rich discussions and knowledge sharing, which are key features of this workshop.

We look forward to a dynamic and engaging meeting, and the chance to see many new and cherished colleagues again in person and virtually.

On behalf of the Organizing Committee,

Kimberly Scarsi, PharmD, MS, FCCP  
Alice Tseng, B.Sc.Pharm., PharmD, FCSHP, AAHIVP

## Program Chairs



**Kimberly Scarsi**  
**PharmD, MS, FCCP**

University of Nebraska  
Medical Center (UNMC),  
United States



**Alice Tseng**  
**B.Sc.Pharm., PharmD,**  
**FCSHP, AAHIVP**

Toronto General Hospital,  
University of Toronto,  
Canada

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**Disclaimer:** This workshop aims to offer participants the opportunity to share information. Virology Education cannot accept any liability for the scientific content of the sessions or for any claims which may result from the use of information or publications from this workshop. Virology Education disclaim all liability for injuries or losses of whatever nature incurred by individuals attending the workshop.



# Meeting Objectives & Learning Objectives

## Meeting Objectives

This meeting aims to:

- Gather experts involved in clinical pharmacology from different disciplines in an interactive workshop setting;
- Provide a platform for presentation and discussion of the latest developments in the field;
- Share information on ongoing pharmacological studies; and
- Stimulate discussion and consensus on best practices.

## Learning Objectives

After this activity, participants will be able to:

- Outline new developments and the clinical pharmacology of antiviral therapies for HIV, COVID-19, hepatitis, and other viruses;
- Reflect on new Drug Detection / Delivery Technologies; and
- Describe pharmacological considerations in key populations.

## Onsite Team



**Jesper Niesen**  
Senior Project Manager  
[Jesper.Niesen@amededu.com](mailto:Jesper.Niesen@amededu.com)



**Michelle Wu**  
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**Daria Bohdanova**  
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[Daria.Bohdanova@amededu.com](mailto:Daria.Bohdanova@amededu.com)



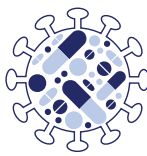
**Zita Hisschemöller**  
Senior AV Coordinator



**Bilal Badi**  
AV Coordinator



**Evita Belegri**  
Scientific Manager



## Abstracts

Accepted abstracts are published in the official abstract book of the **International Workshop on Clinical Pharmacology of HIV, Hepatitis, and Other Antiviral Drugs 2023**. The abstract book is available on the workshop's webpage.

## Badge Policy

All registered delegates are provided with an identity badge. Please wear your badge at all times to ensure admission to the workshop. No spare badges can be issued.

## Certificate of Attendance

The certificate of attendance will be sent by e-mail to participants that have successfully completed the program and filled in the post-workshop survey.

## Code of Conduct

All individuals are required to observe our Code of Conduct. We do not tolerate any form of discrimination, harassment, disrespect, or the marginalization of those involved in our programs. Please report any incidents to VE and AME via [info@amededu.com](mailto:info@amededu.com) or to one of our onsite personnel. Any participant who is found to have exhibited any inappropriate conduct or behavior against others may be removed from the program.



**View Code of Conduct in Full:**  
[www.AcademicMedicalEducation.com/our-commitment-diversity-and-inclusion](http://www.AcademicMedicalEducation.com/our-commitment-diversity-and-inclusion)

## Meeting Language

The official language of the meeting is English.

## Enduring Materials

**ame** Webcasts of the presentations, along with the PDF presentations will be available on: [www.AcademicMedicalEducation.com](http://www.AcademicMedicalEducation.com) shortly after the workshop, assuming we have received the speakers' permission to do so.

## Feedback Form

Your feedback is very valuable to us and enables us to further improve this program. At the end of each workshop day, a survey will be sent to you via e-mail. We would like to ask you to complete it.

## Networking Opportunities

Make use of the options to network during the coffee breaks, lunches, poster reception, and networking dinner. The poster reception is accessible to all onsite registered delegates and is included in the registration fee. The networking dinner is available to all onsite registered delegates for an additional fee. Please contact the onsite team if you would like to purchase a ticket. The dinner takes place on **Tuesday, 12 September 2023 at 19:00 CEST**.

## Posters

During the workshop, all accepted posters are displayed in the virtual poster gallery. The poster gallery is always open for you.

For those attending in-person, there will be a poster viewing session and reception at the end of Day 1 on **Monday, 11 September 2023 at 17:35 CEST**.

## Social Media

We encourage you to post news and tweet about **#AntiviralPK** on your social media accounts during the workshop. You can either post your own tweets or retweet a message from the official [@Academic\\_MedEdu](https://twitter.com/Academic_MedEdu).

## Time Zones

Times are in Central European Summer Time (CEST). If you need to convert the times to your timezone, this website might be of interest to you: [www.WorldTimeBuddy.com](http://www.WorldTimeBuddy.com).

## Venue

The **International Workshop on Clinical Pharmacology of HIV, Hepatitis, and Other Antiviral Drugs 2023** will be held at the Roma Eventi Fontana Di Trevi, Rome, Italy.

## Virtual Platform

OnAIR is the virtual platform that will be used for the **International Workshop on Clinical Pharmacology of HIV, Hepatitis, and Other Antiviral Drugs 2023** for those attending virtually. The recordings of this meeting will be available on the virtual platform until approximately 3 weeks after the closure of the meeting.

## Wi-Fi

Wi-Fi will be available throughout the duration of the workshop.

## Organizing Committee



**Kimberly Scarsi**  
**PharmD, MS, FCCP**

University of Nebraska Medical Center  
(UNMC),  
United States



**Alice Tseng**  
**B.Sc.Pharm., PharmD, FCSHP, AAHIVP**

Toronto General Hospital, University of  
Toronto,  
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**Peter L. Anderson**  
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**Marta Boffito**  
**MD, PhD, FRCP**

Chelsea and Westminster Hospital London,  
United Kingdom



**Andrea Calcagno**  
**MD, DTM&H**

University of Turin,  
Italy



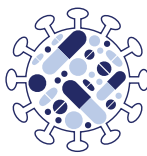
**Tim Cressey**  
**MSc, PhD**

Chiang Mai University,  
Thailand

## Scientific Committee

<b>Su-Young Choi, PharmD, PhD</b>	Food and Drug Administration, United States
<b>Angela Colbers, PhD</b>	Radboud University Medical Center, the Netherlands
<b>Rodolphe Garraffo, MD</b>	Hopital Pasteur Nice, France
<b>David Haas, MD</b>	Vanderbilt University Medical Center, United States
<b>Saye Khoo, MD</b>	University of Liverpool, United Kingdom
<b>Mohammed Lamorde, MD</b>	Infectious Diseases Institute, Uganda
<b>Lawrence Lee, MBBS, PhD</b>	National University of Singapore, Singapore
<b>Minh Patrick Lê, PhD</b>	Hôpital Bichat-Claude Bernard, France
<b>Catia Marzolini, PharmD, PhD</b>	University Hospital Basel & University of Liverpool, United Kingdom
<b>Kimberly Struble, PharmD</b>	Food and Drug Administration, United States
<b>Steve Taylor, MRCP, PhD</b>	Birmingham Heartlands Hospital, United Kingdom
<b>Catriona Waitt, MBChB, PhD</b>	University of Liverpool, United Kingdom





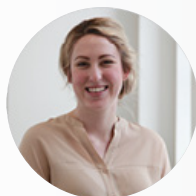
## Academic Advisory Board

<b>David Back, PhD</b>	University of Liverpool, United Kingdom
<b>Terrence Blaschke, MD</b>	Stanford University School of Medicine, United States
<b>David Burger, MD, PhD</b>	Radboud University Medical Center, the Netherlands
<b>Giovanni Di Perri, MD, PhD</b>	University of Torino, Italy
<b>Courtney Fletcher, PharmD</b>	University of Nebraska Medical Center, United States
<b>Charles Flexner, MD</b>	Johns Hopkins University, United States
<b>Angela Kashuba, PharmD</b>	University of North Carolina at Chapel Hill, United States
<b>Jennifer Kiser, PharmD, PhD</b>	University of Colorado, United States
<b>Jürgen Rockstroh, MD</b>	University of Bonn, Germany
<b>Jonathan Schapiro, MD</b>	National Hemophilia Center, Sheba Medical Center, Israel

## Industry Liaison Board

<b>Wei Liu - AbbVie</b>
<b>Thomas Kakuda - Alios BioPharma</b>
<b>Charles LaPorte - Janssen Biologics</b>
<b>Marco Siccardi - Labcorp</b>
<b>Daria Hazuda - Merck</b>
<b>Manoli Vourvahis - Pfizer</b>
<b>Parul Patel - ViiV Healthcare</b>

# Speakers



**Lauren Walker, MBChB (Hons), PhD,  
MRCP (UK), PGCAP, FHEA, FBPhS**  
University of Liverpool,  
United Kingdom



**Nancy Sheehan, PharmD, MSc**  
Université de Montréal and McGill  
University Health Centre,  
Canada



**Minh Patrick Lê, PharmD, PhD**  
University of Paris Cité, Bichat-  
Claude Bernard Hospital,  
France



**Catriona Waitt, MBChB, PhD**  
University of Liverpool,  
United Kingdom



**Catherine Chappell, MD, MSc**  
University of Pittsburgh,  
United States



**Andrew Owen, BSS, MSc, PhD, FSB**  
University of Liverpool,  
United Kingdom



**Emma Rubenstein, MD, MPH**  
Hôpital Saint-Louis,  
France



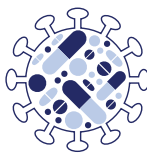
**Mike Emerson, PhD**  
Imperial College London,  
United Kingdom



**Catia Marzolini, PharmD, PhD**  
University Hospital of Basel,  
University Hospital of Lausanne,  
Switzerland;  
University of Liverpool,  
United Kingdom



**Dario Cattaneo, PharmD, PhD**  
Luigi Sacco University Hospital,  
Italy



**Giovanni Di Perri, MD, PhD**  
University of Turin,  
Italy



**Paolo Denti, PhD**  
University of Cape Town,  
South Africa



**Elin Lindhagen, MSci Pharm, PhD**  
Swedish Medical Products Agency,  
Sweden



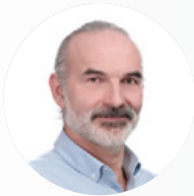
**Alice K. Pau, PharmD, FIDSA**  
National Institute of Allergy and  
Infectious Disease, National  
Institutes of Health,  
United States



**Ramesh Palaparthi, PhD**  
Gilead Sciences,  
United States



**Jon Collins, PharmD**  
ViiV Healthcare,  
United States



**Simon Portsmouth, MBChB, MD,  
FRCP**  
Shionogi Inc.,  
United States



**Xiao-Jian Zhou, PhD**  
Atea Pharmaceuticals, Inc., United  
States  
[View Bio >](#)



**Charles Flexner, MD**  
Johns Hopkins University  
School of Medicine,  
United States

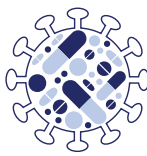


**Saye Khoo, MD, PhD**  
Royal Liverpool University Hospital;  
University of Liverpool,  
United Kingdom

## Monday, 11 September 2023

Central European Summer Time (CEST)

Opening of the Workshop	
14:00	<p><b>Introduction by the Chairs</b>  <b>Kimberly Scarsi, PharmD, MS, FCCP</b>                      University of Nebraska Medical Center (UNMC), United States  <b>Alice Tseng, B.Sc.Pharm., PharmD, FCSHP, AAHIVP</b>                      Toronto General Hospital, University of Toronto, Canada</p>
14:10	<p><b>Opening Lecture: News in Antiviral Pharmacology: A Year in Review</b>  <b>Andrea Calcagno, MD, DTM&amp;H</b>                      University of Turin, Italy</p>
14:30	<p><b>The Use of AI in Clinical Pharmacology</b>  <b>Lauren Walker, MBChB (Hons), PhD, MRCP (UK), PGCAP, FHEA, FBPhS</b>                      University of Liverpool, United Kingdom</p>
Session 1 Perspectives on the Role of ARV TDM in Clinical Pharmacology Session Chair: Saye Khoo & Alice Pau	
15:05	<p><b>Is TDM Still Needed/Useful?</b>  <b>Nancy Sheehan, PharmD, MSc</b>                      Université de Montréal and McGill University Health Centre, Canada</p> <p><b>Minh Patrick Le, PharmD, PhD</b>                      University of Paris Cité, Bichat-Claude Bernard Hospital, France</p>
15:35	<b>Discussion</b>
15:50	<b>Coffee Break</b>
Session 2 Special Topics in Clinical Pharmacology - Key Populations Session Chairs: Tim Cressey & Laura Dickinson	
16:20	<p><b>New(er) Antiretrovirals in Pregnancy and Breastfeeding</b>  <b>Catriona Waitt, MBChB, PhD</b>                      University of Liverpool, United Kingdom</p>
16:40	<p><b>Pharmacokinetics of Sofosbuvir-Based Direct Acting Antivirals for HCV in Pregnancy</b>  <b>Catherine Chappell, MD, MSc</b>                      University of Pittsburgh, United States</p>
17:00	<p>Antiretroviral Drug Exposure and Response in Obese and Morbidly Obese People with HIV #1  <b>Mattia Berton</b>                      University Hospital Basel, Switzerland</p>
17:10	<p>Pharmacokinetic Data of Atazanavir/Ritonavir in Second-Line Treatment of Children Living with HIV: Results from the CHAPAS4-trial. #2  <b>Anne Kamphuis</b>                      Radboud University Medical Center, The Netherlands</p>
17:20	<b>Discussion</b>
17:35	<b>Poster Viewing Session &amp; Reception</b>
18:30	<b>End of Day 1</b>



## Tuesday, 12 September 2023

Central European Summer Time (CEST)

### Session 3 Next-Generation Therapeutics – Long-Acting Drugs

Session Chairs: *Catia Marzolini & Minh Patrick Lê*

9:00 **Knowledge Gaps and Future Perspectives for Treatment Based on Long-Acting Technology**

**Andrew Owen, BSS, MSc, PhD, FSB**

University of Liverpool, United Kingdom

9:20 **A Year of CAB/RPV Use, What Have We Learned in the Real World**

**Emma Rubenstein, MD, MPH**

Hôpital Saint-Louis, France

9:40 Preliminary Results of Therapeutic Drug Monitoring of Long-Acting Cabotegravir and Rilpivirine in a Large National Cohort of People Living with HIV (ANRS-MIE-CARLA Study) #3

**Caroline Solas Chesneau**

University Hospital of La Timone, Aix-Marseille University, France

9:50 **Discussion**

10:05 **Coffee Break**

### Session 4 Abstract-Driven Session on Clinical Pharmacology in Pregnancy and HIV

Session Chairs: *Angela Colbers & Catriona Waitt*

10:45 Intracellular Tenofovir-Diphosphate Concentrations with Tenofovir Alafenamide During Pregnancy and Postpartum in People with HIV: Results from IMPAACT 2026 #5

**Kristina Brooks**

University of Colorado Anschutz Medical Campus, United States

10:55 Temporal Changes in Dolutegravir and Raltegravir Glucuronide Metabolite to Parent Ratios during Pregnancy and Postpartum #6

**Tim Cressey**

Chiang Mai University, Thailand

11:05 Lower Exposure to Bictegravir in Third Trimester in Pregnant Women Living with HIV #7

**Lena Van Der Weken**

Radboudumc, The Netherlands

11:15 Prediction of Maternal Pharmacokinetic of Bictegravir in Pregnancy Using Physiologically-Based Pharmacokinetic Modeling #8

**Jeihun Kuack**

U.S. Food And Drug Administration, United States

11:25 **Discussion**



## Session 5 Challenges in Managing Complex Drug - Drug Interactions

Session Chairs: Marta Boffito & Nancy Sheehan

- 11:40 **Management of Antiplatelet/DOAC DDIS (Pk/PD) - in Context of HIV, HCV, COVID Antiviral Therapy**  
**Mike Emerson, PhD**  
 Imperial College London, United Kingdom
- 12:00 **Short versus Extended Nirmatrelvir/R Treatment Course and Ensitrelvir: How Do DDI's Differ?**  
**Catia Marzolini, PharmD, PhD**  
 University Hospital of Basel, University Hospital of Lausanne, Switzerland; University of Liverpool, United Kingdom
- 12:20 **Case Presentation - Complex DDI Case**  
**Dario Cattaneo, PharmD, PhD**  
 Luigi Sacco University Hospital, Italy
- 12:35 **Case Presentation - Complex DDI case**  
**Giovanni Di Perri, MD, PhD**  
 University of Turin, Italy

12:50 **Discussion**

13:05 **Lunch Break**

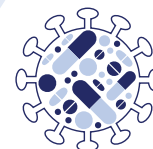
## Session 6 Drug Interactions: PBPK Modelling and Pharmacodynamic Outcomes

Session Chairs: Andrea Calcagno & Kristina Brooks

- 14:05 **DDIs Between Long-Acting Antiretroviral and TB Drugs for Prevention and Treatment**  
**Paolo Denti, PhD**  
 University of Cape Town, South Africa
- 14:25 Physiologically Based Pharmacokinetic Modeling of Lenacapavir Pharmacokinetics and Model Validation with Drug-Drug Interactions Between Lenacapavir with Voriconazole or Rifampicin #9  
**Naveed Shaik**  
 Gilead Sciences, Inc., United States
- 14:35 Dolutegravir But not Bictegravir Exposure Increases in Vitro Platelet Aggregation #10  
**Renos Keniyopoulos**  
 Imperial College London, United Kingdom
- 14:45 Genetic Variants Influencing Neuroinflammation Biomarkers in Different Clinical Groups of People Affected by HIV #11  
**Jessica Cusato**  
 University of Turin, Department of Medical Sciences, Italy

14:55 **Discussion**

15:10 **Refreshments & Poster Viewing**



## Session 7 DDI Guidance: Regulatory Landscape and Challenges With Emerging/New Compounds

Session Chair: Charles Flexner

- 15:55 **Harmonization of DDI Guidelines Among Different Regulatory Agencies: Challenges and Opportunities**  
**Elin Lindhagen, MSci Pharm, PhD**  
Swedish Medical Products Agency, Sweden
- 16:15 **A Global Collaboration to Harmonize Guidelines for Clinical Management of Ritonavir-Boosted Nirmatrelvir DDIs**  
**Alice K. Pau, PharmD, FIDSA**  
National Institute of Allergy and Infectious Disease, National Institutes of Health, United States
- 16:35 **Discussion**
- 16:50 Nirmatrelvir/Ritonavir Real World Drug-Drug Interaction Management Experience #12  
**Shahid Bukhari**  
Chelsea & Westminster Hospital, United Kingdom
- 17:00 A Retrospective Descriptive Study of the Management and Consequences of Drug-Drug Interactions between Nirmatrelvir/Ritonavir and Systemic Treatment for Cancer #13  
**Samantha Robertson**  
Kingston Health Sciences Centre, Canada
- 17:10 Management of Drug-Drug Interaction and Safety of Oral Anticoagulants with Nirmatrelvir-Ritonavir #14  
**Pierre Giguere**  
The Ottawa Hospital, Canada
- 17:20 **Discussion**
- 17:35 **End of Day 2**
- 19:00 **Networking Dinner**

## Wednesday, 13 September 2023

Central European Summer Time (CEST)

## Session 8 Pharmacologic Data on New and Pipeline Drugs - Industry Session

Session Chair: Giovanni di Perri

- 8:30 **Gilead Sciences**  
**Ramesh Palaparthi, PhD**  
Gilead Sciences, United States
- 8:45 **GSK - ViiV Healthcare**  
**Jon Collins, PharmD**  
ViiV Healthcare, United States
- 9:00 **Shionogi Inc.**  
**Simon Portsmouth, MBChB, MD, FRCP**  
Shionogi Inc., United States
- 9:15 **Atea Pharmaceuticals Inc.**  
**Xiao-Jian Zhou, PhD**  
Atea Pharmaceuticals, Inc., United States
- 9:15 **Discussion**

9:45 **Coffee Break & Poster Viewing**

## Session 9 Abstract-Driven Session on Innovative Tools to Assess Drug Exposure and Adherence

Session Chairs: Peter Anderson & Anthony Podany

- 10:15 Adherence Blood Sampling Devices Are Not All Created Equal: A Comparative Investigation #15  
**Amanda Schauer**  
 University of North Carolina-Chapel Hill, United States
- 10:25 PrEP at the Site-of-Action in Transgender Women: A Pharmacology Study of Blood and Rectal CD4+ T Lymphocytes #16  
**Mackenzie L. Cottrell**  
 University of North Carolina, Chapel Hill, United States
- 10:35 Saliva, Tear and Nasal PK of Ritonavir-boosted Nimatrelvir (Paxlovid) in Combination with Molnupiravir in Patients with Laboratory Confirmed COVID-19 #17  
**Laura Dickinson**  
 University of Liverpool, United Kingdom
- 10:45 A Novel Approach to Identify PK Determinants of Efficacy: Implications for HIV-1 Latency Reversal by Romidepsin #18  
**Lauren Tompkins**  
 The University of North Carolina at Chapel Hill, United States

10:55 **Discussion**

### Charles Boucher Memorial Session: The Role of Tissue Pharmacology in Clinical Response and Cure

Session Chair: Steve Taylor

- 11:10 **Tissue-Specific Pharmacology: Knowledge and Knowledge Gaps**  
**Charles Flexner, MD**  
 Johns Hopkins University School of Medicine, United States
- 11:30 **Tissue-Specific Pharmacology: How Clinically Important Is It**  
**Saye Khoo, MD, PhD**  
 Royal Liverpool University Hospital; University of Liverpool, United Kingdom

11:50 **Discussion**

### Closing of the Workshop & Abstract Awards

- 12:05 **Closing Remarks**  
**Kimberly Scarsi, PharmD, MS, FCCP**  
 University of Nebraska Medical Center (UNMC), United States  
**Alice Tseng, B.Sc.Pharm., PharmD, FCSHP, AAHIVP**  
 Toronto General Hospital, University of Toronto, Canada

12:15 **End of Workshop**



## Corporate Support

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