NIFDS-DIA Workshop 2021

Facilitating the Development and Regulations of Covid-19 Vaccines and Treatments/ Current Trends in New Drug Development and Regulations

SEP 02. 2021 09:30AM ~ SEP 03. 2021 15:30PM (Korea Local Time), Virtual Event

Advisory Committee

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Director General of NIFDS

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In response to the continuing COVID-19 crisis, regulatory authorities have focused on providing support for the rapid development of vaccines and treatments and the expedited approval and implementation of agile regulatory systems.

The NIFDS-DIA Workshop 2021 will explore the theme of "Facilitating the Development and Regulations of COVID-19 Vaccines and Treatments /Current Trends in New Drug Development and Regulations."

NIFDS and DIA jointly offer you an opportunity to share experiences of systematic and effective response to the global crisis caused by the COVID-19 pandemic. We will invite former and current regulators in the FDA and EMA as well as experts from the pharmaceutical industry who have hands-on experiences.

We will also hear from speakers about innovative drug develpment. tools used and legal strategies.

Highlights

- Regulatory Trends in Response to COVID-19
- COVID-19 Treatment Development Experiences
- COVID-19 Vaccine Development Strategy
- Korea's Strategy for Going Global
- Effective Method for Accelerating Drug Development
- Development of Innovative Drugs

Registration

Please go to :
https://www.diaglobal.org/en/conference-listing/meetings/2021/09/dia-nifds-workshop-2021-facilitating-the-development-and-regulations-of-covid-19-vaccines-and-treatments-current-trends-in-new-drug-development-and-regulations

AGENDA | Day 1 | September 2, 2021

Korea Local Time

8:50-9:30 **Welcome and Registration**

9:30-9:40 **Opening Remarks & Keynote Presentation - NIFDS's Response and Strategy against COVID-19**

Dr. Kyung Won Seo
NIFDS, Director General of NIFDS

Session 1 : Regulatory Trends in Response to COVID-19

Session Chair
Dr. Hae-Young Ahn
Ahn Bio

9:40-10:00 **Facilitating the Development and Availability of COVID-19 Vaccine**

Dr. Peter Marks
FDA

10:00-10:20 **Efforts to Facilitate the Development of Anti-SARS-CoV-2 Monoclonal Antibodies**

Dr. John Farley
FDA

10:20-11:00 **Assessment, Authorization and Monitoring of EU COVID-19 Vaccines in the Context of a Pandemic**

Thomas Larsson
EMA

11:00-11:40 **Consideration on the Development of Vaccines and Treatments in terms of Expedited Review**

Dr. Gi Hyun Kim
NIFDS

11:40-13:00 Lunch

Session 2 : COVID-19 Treatment Development Experiences

Session Chair
Dr. Jeewon Joung
NIFDS

13:00-13:40 **Development Strategy of Molnupiravir**

De Anda, Carisa Stadlman
MSD

13:40-14:20 **A Case Study : History of Expedited Development of Regkirona inj (Regdanvimab)**

Minsoo Kim
Celltrion

14:20-15:00 **Key Points in the Development of COVID-19 Treatments Based on Clinical Trial Experience**

Jin Yong Kim
INCHEON Medical Center

15:00-15:20 Coffee Break

Session 3 : COVID-19 Vaccine Development Strategy

Session Chair
Dr. Jaeok Kim
NIFDS

15:20-16:00 **BNT162b2 COVID-19 Vaccine - From Hope to Reality in 9 Months**

Dr. James Baber
Pfizer

16:00-16:40 **Development of Next Generation mRNA COVID-19 Vaccine**

Yu Hwa Choi
Quratis Inc.

16:40-17:20 **Considerations for COVID-19 Vaccine Clinic Trials**

Won Suk Choi
Korea University Ansan Hospital

17:20-17:30 **Closing Remarks**

Dr. So Hee Kim
NIFDS

AGENDA | Day 2 | September 3, 2021

Korea Local Time

9:30-9:40 **Access to Innovative Medicines in Korea**

Dr. Younjoo Park
NIFDS, Direct General

Session 4 : Korea's Strategy for going Global

Session Chair
Dr. JuneSik Mune
LG Chem

9:40-10:00 **America's Global Patent Protection Strategy during New Drug Development**

Meejeong Lee
SK biopharmaceuticals

10:00-10:20 **New Drug Development and IP Strategy**

Kyung Ae Yoon
YULCHON LLC

10:20-11:00 **Clinical Development Strategy**

Sun Young Yum
Bridge Biotherapeutics Inc.

11:00-11:20 Coffee Break

Session 5 : Effective Method for Accelerating Drug Development

Session Chair
Dr. Younglim Kim
NIFDS

11:20-12:00 **Statistical Considerations in Safety Evaluation during the Life Cycle of A Drug Product**

Dr. Jessica Kim
FDA

12:00-12:40 **Use of Real-World Data and Real-World Evidence in Drug Development and Approvals**

Dr. Joo Yeon Lee
FDA

12:40-14:00 Lunch

Session 6 : Development of Innovative Drug

Session Chair
Dr. Heesung Kim
NIFDS

14:00-14:40 **CMC Considerations for Accelerated Development of Advanced Therapy Products**

Dr. Jun Park
ILIAS Biologics

14:40-15:20 **Clinical Trials for Expedited Review and Development Programs**

Dr. Hae-Young Ahn
Ahn Bio

15:20-15:30 **Closing Remarks**

Dr. Youngju Choi
NIFDS

NIFDS-DIA Workshop 2021 – Facilitating the Development and Regulations of COVID-19 Vaccines and Treatments / Current Trends in New Drug Development and Regulations
Event I.D. 83521 | September 2-3, 2021 | Virtual Meeting

2-3 September, 2021 : Grand Ballroom, H Hotel Sejong City, Osong, Cheongju
Address: 178 Osongsaengmyeong ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do
T: 0507-1419-4800

(Only speakers and session chairs can attend this workshop on site)

CANCELLATION POLICY: ON OR BEFORE AUGUST 24, 2021

- Cancellations must be in writing and received by August 24, 2021. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.
- DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.
- UPON CANCELLATION, the administrative fee that will be withheld from refund amount is 25 % of the delegate fee.

FULL MEETING CANCELLATION

- All refunds will be issued in the currency of the original payment.

For more details, please visit https://www.diaglobal.org/en/conference-listing/meetings/2021/09/dia-nifds-workshop-2021-facilitating-the-development-and-regulations-of-covid-19-vaccines-and-treatments-current-trends-in-new-drug-development-and-regulations

REGISTRATION FEES FOR TWO DAYS WORKSHOP

Early Bird (Until Aug 24, 2021)
(Subject to Payment Realization)

	Registration Fee (KRW)
Industry - Member	125,000 ❑
Industry Non-Member	150,000 ❑
Academia	100,000 ❑
Government	25,000 ❑

Standard Rates (After Aug 25, 2021)
(Subject to Payment Realization)

Industry-Member	175,000 ❑
Industry Non-Member	200,000 ❑
Academia	150,000 ❑
Government	30,000 ❑

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DIA Membership	USD
1-Year Membership	230
2-Year Membership	430

REGISTRATION

Register online at the link below or complete this registration form and email to our Japan Office.

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Email: Japan@diaglobal.org

ONLINE REGISTRATION

For Payment via Credit Card, please access the link:
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