

16 March 2020

10:15-15:00

Workshop

Ready for Translation?

The role of supporting preclinical evidence
in justifying phase I/II trials
with somatic genome editing

KEY NOTE

Philip John (P.J.) Brooks

Working Group Coordinator,
NIH Common Fund program on Somatic Cell
Genome Editing

NCATS Program Director,
Office of Rare Diseases Research

Program

10:15 Intro: Daniel Strech, BIH QUEST Center/Charité

**10:30 Reporting of robustness criteria in results
publications for preclinical genome editing,** Merlin
Bittlinger, BIH QUEST Center/Charité

**10:45 Reporting of supporting preclinical evidence in
investigator brochures (IBs) for phase I/II trials,** Susanne
Wieschowski, Hannover Medical School

**11:00 KEY NOTE: The NIH/NCATS funding requirements for
confirmation in preclinical somatic genome editing:
Rationale and experiences,** PJ Brooks, NIH/NCATS

**11:45 The new BMBF funding scheme for confirmatory
preclinical studies & and the accompanying DECIDE
project,** Ulf Tölch, BIH QUEST Center/Charité

12:00 Lunch

13:15 Open discussion / Future directions
What should we expect from supporting evidence for phase
I/II trials?

14:45 Summary / Outlook

15:00 End of Workshop

Venue

BIH QUEST Center
Anna-Louisa-Karsch-Str. 2, 5th floor
10178 Berlin

Getting there

S-Bahn, stop Hackescher Markt
see also:

<https://www.bihealth.org/en/about-us/contact/>

Contact & registration

Registration is required via e-mail
by 10th March to:

konstanze.scheurer@charite.de

Tel. + 30 450 543676

<https://www.bihealth.org/en/>

Funding

The workshop is funded by the BMBF-sponsored
project GEENGOV-Governance of Biomedical
Genome Editing

GEFÖRDERT VOM



Bundesministerium
für Bildung
und Forschung