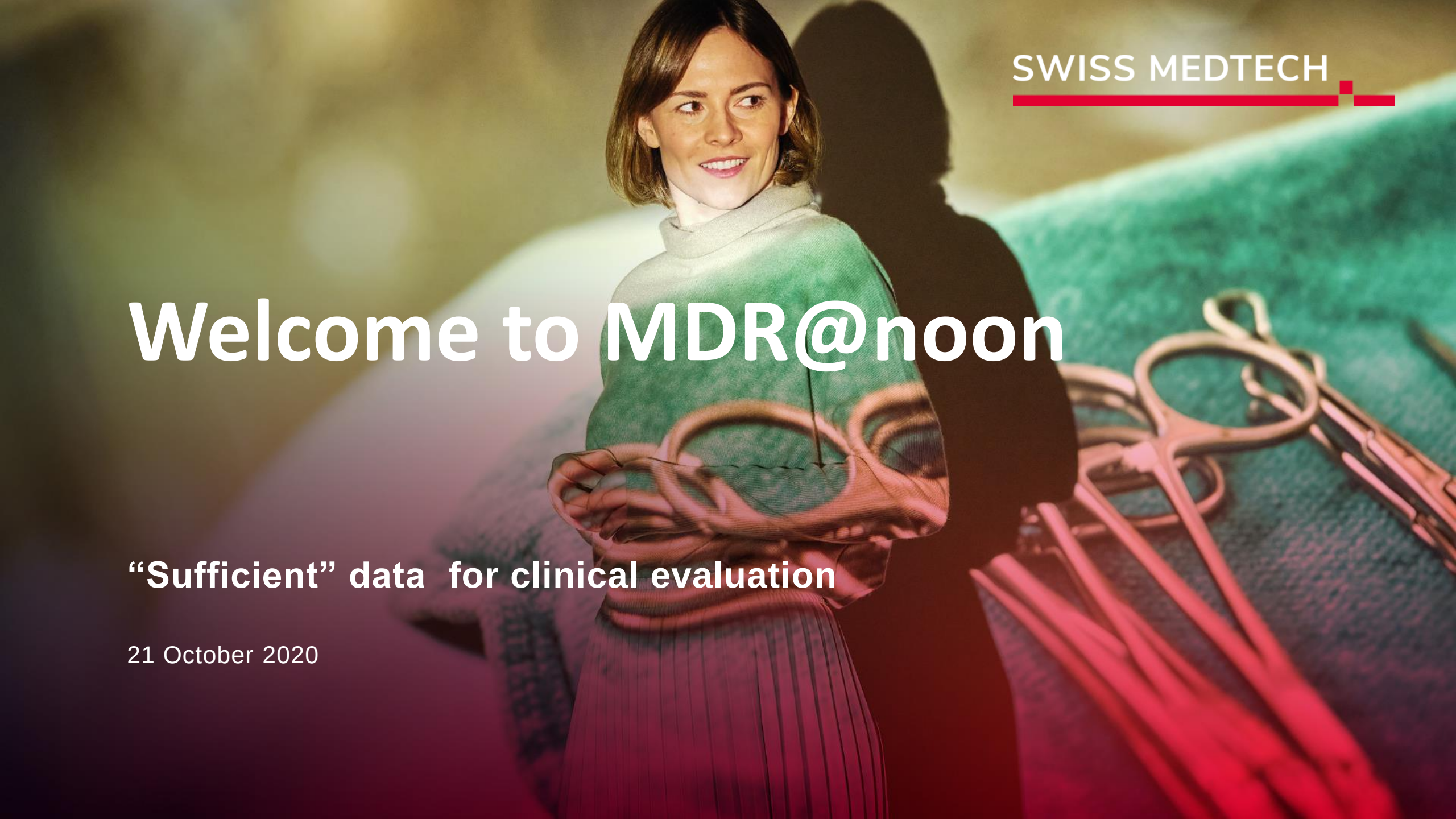

SWISS MEDTECH

Welcome to MDR@noon

“Sufficient” data for clinical evaluation

21 October 2020

SWISS MEDTECH

MDR@noon

"SUFFICIENT" DATA FOR CLINICAL EVALUATION

PETER MÜNGER (MATHYS LTD BETTLACH)
HEAD OF MEDICAL AFFAIRS
How do we define “sufficient data” for the clinical evaluation of our medical products?

PAVEL BUNCAK (VIGILANX)
HEAD OF MEDICAL AFFAIRS
A new tool to keep track of your vigilance data

JASMINKA ROTH (TAO OF EXCELLENCE)
DIRECTOR AND FOUNDER
How to appreciate clinical data

"Sufficient" data for clinical evaluation

What does the MDR say?

Article 61

Clinical evaluation

The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

MDR@noon Rules

Participants on mute

Camera off

Questions via chat

Session recorded

Host: Daniel Delfosse, Head of RA

Pdf and recording available on homepage: https://www.swiss-medtech.ch/