

# MISSION IMPOSSIBLE? DM AND SITES COLLABORATION

Julia Kwaśnikowska

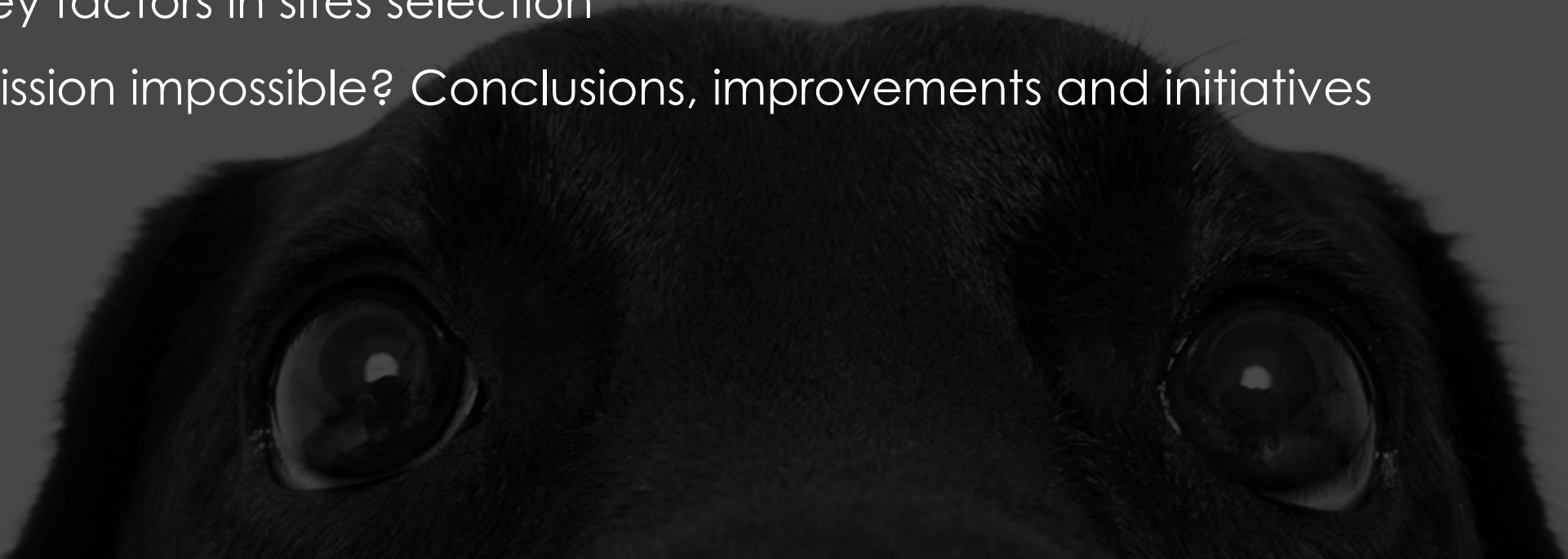
Clinical Data and Insights, Clinical Operations, R&D, AstraZeneca, Warsaw, Poland

Mateusz Uchacz

Clinical Data and Insights, Clinical Operations, R&D, AstraZeneca, Warsaw, Poland

# AGENDA

- Collaboration with sites
- Why cooperate?
- ICH GCP and stakeholders
- Methodology
- Key factors in sites selection
- Mission impossible? Conclusions, improvements and initiatives



# DISCLAIMER

The opinions expressed in this presentation are that of the presenter and are not necessarily the opinions of AstraZeneca.



# BIO

## Julia

- Associate Director,  
Study Data Manager
- Working in the industry since 2015
- Focused on collaboration aspect within study teams
- Always on the move

## Mateusz

- Associate Director,  
Study Data Manager
- Fascinated by developing strategies for new processes and driving innovations
- Mountain lover
- Brazilian jiu-jitsu practitioner

A photograph of a misty forest path. On the left, a large, moss-covered tree trunk dominates the foreground. A dirt path winds through the dense, green forest towards the background, where a small figure of a person can be seen. The atmosphere is soft and ethereal due to the mist.

# COLLABORATION WITH SITES

Shifting from a shadowy forest trail to a brightly lit path

# WHY COOPERATE?

---

To discover practical implementation of the newest ICH GCP Guide

---

To tighten cooperation with sites

---

To identify unmet needs of sites and patients

---

To evaluate the potential process updates

---

To induce a permanent effect in WoW



# ICH GCP AND STAKEHOLDERS

## 3.3.3. Engaging stakeholders in study design

Clinical study design is best informed by input from a broad range of stakeholders, including patients and healthcare providers. It should be open to challenge by subject matter experts and stakeholders from outside, as well as within, the sponsor organisation.

The process of building quality into the study may be informed by participation of those directly involved in successful completion of the study such as clinical investigators, study coordinators and other site staff, and patients/patient organisations. Clinical investigators and potential study participants have valuable insights into the feasibility of enrolling participants who meet proposed eligibility criteria, whether scheduled study visits and procedures may be overly burdensome and lead to early dropouts, and the general relevance of study endpoints to the target patient population. They may also provide insight into the various cultural issues, culture, region, demographics, and other characteristics of the target population.

Early engagement with regulatory authorities is encouraged and key elements considered critical to quality (e.g., defining patient



INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL  
REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

Sources: [https://database.ich.org/sites/default/files/E8-R1\\_Guideline\\_Step4\\_2021\\_1006.pdf](https://database.ich.org/sites/default/files/E8-R1_Guideline_Step4_2021_1006.pdf)

[https://www.ema.europa.eu/en/documents/scientific-guideline/draft-ich-guideline-e8-r1-general-considerations-clinical-studies-step-2b\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/draft-ich-guideline-e8-r1-general-considerations-clinical-studies-step-2b_en.pdf)

# FROM GRASSROOTS WORK TO THE ESSENCE OF THE PROBLEM



Tailor-made methodology for collecting feedback



Developing of collaboration between global and local teams



Study DM leads on sites



CRAs involved

# METHODOLOGY

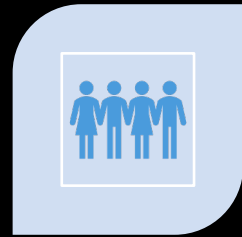
- Questionnaires
- Examples of questions used:
  - ‡ When working at EDC, do you see any duplication of work with other roles?
  - ‡ Which of the processes in the study pose the greatest challenges and could be improved?
  - ‡ As a site, during milestone preparation, do you see a need to do something differently to help you follow through and meet the requirements?



# KEY FACTORS IN SITES SELECTION



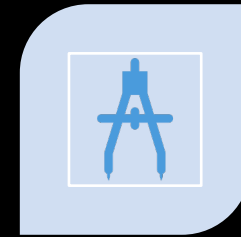
PHASE OF THE  
STUDY



NUMBER OF  
PATIENTS



STUDIES ON SITE

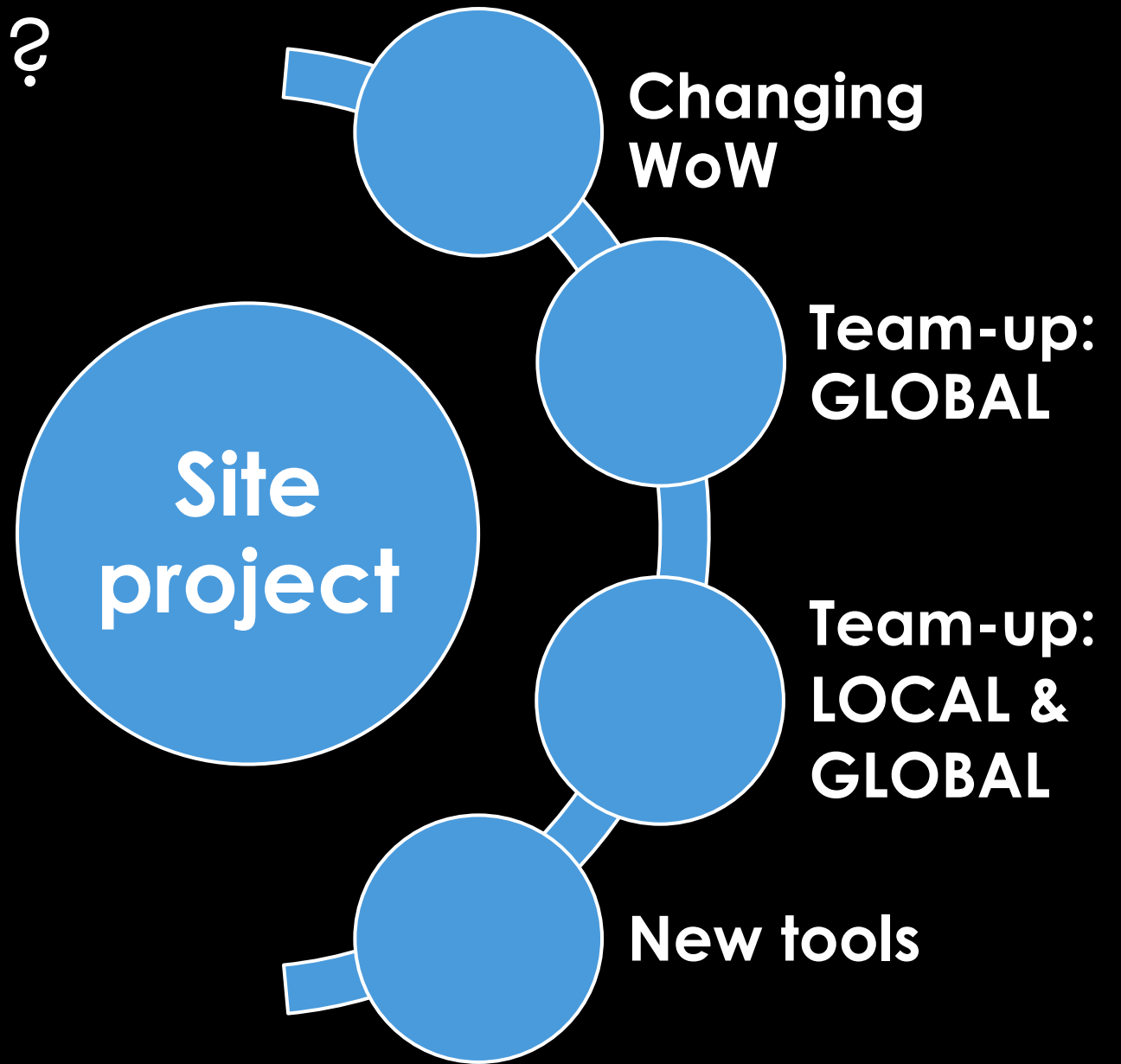


COMPLEXITY OF  
STUDIES ON SITE

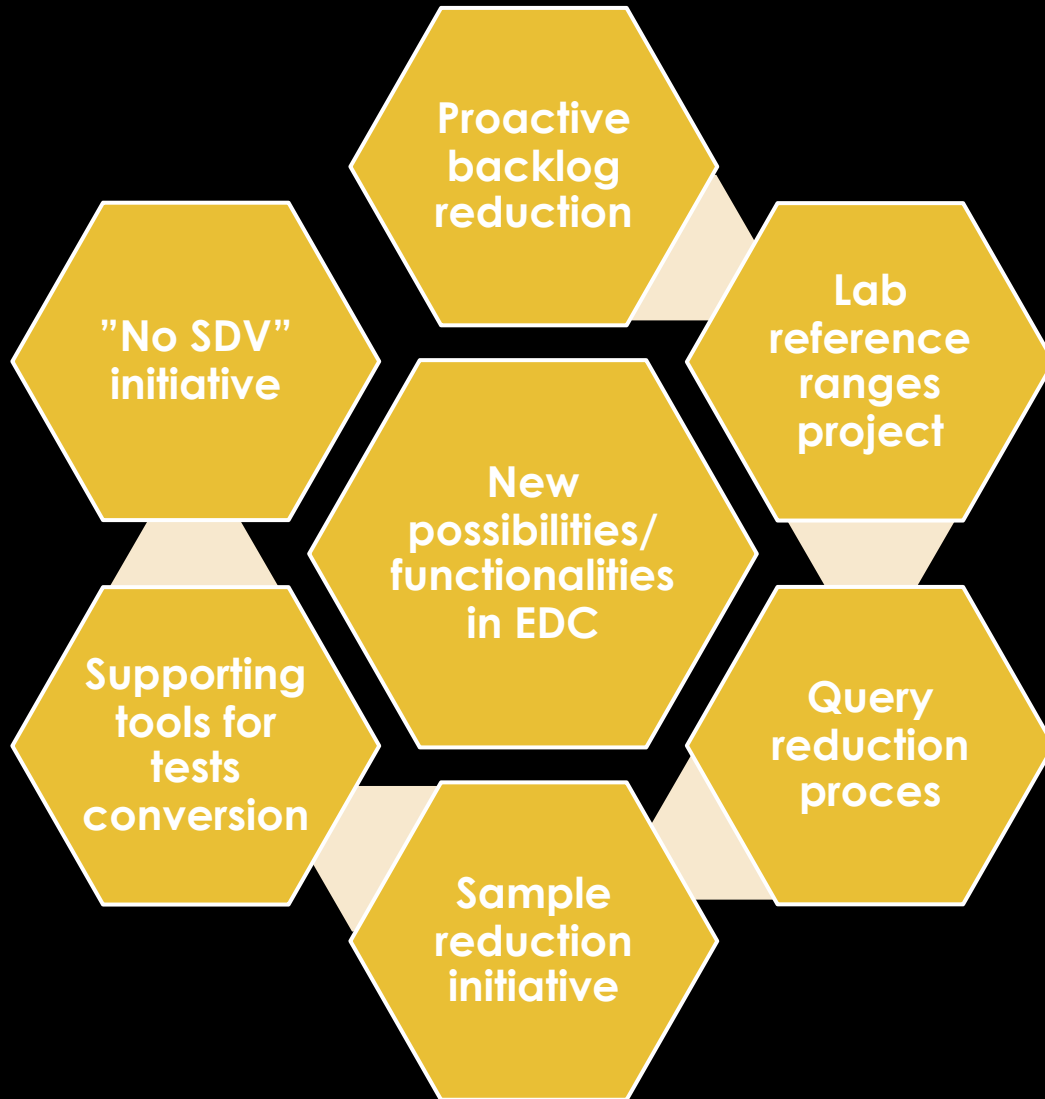


AVAILABILITY OF  
DM LEAD AND CRA

# MISSION IMPOSSIBLE?



# IMPROVEMENTS AND INITIATIVES



# ADDITIONAL BENEFITS



Process fixed, simplified or created



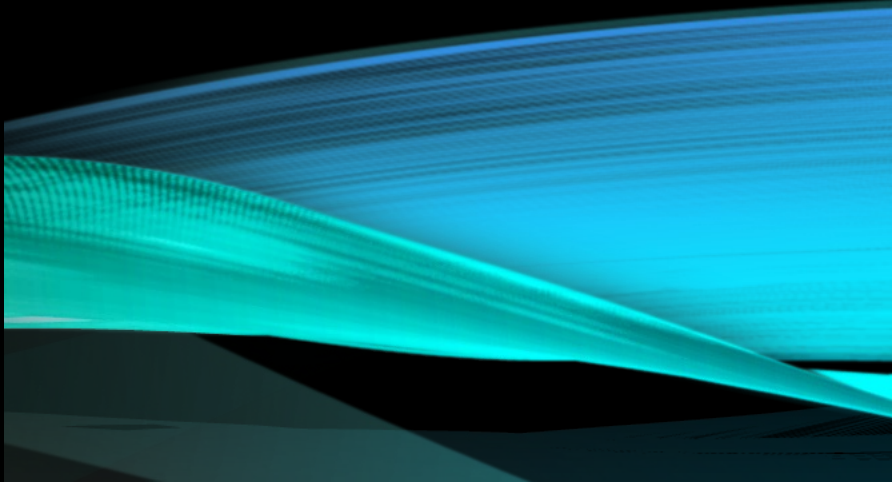
Mutual understanding



Tightening the cooperation



Q&A





# THANK YOU!

[julia.kwasnikowska@astrazeneca.com](mailto:julia.kwasnikowska@astrazeneca.com)

[mateusz.uchacz@astrazeneca.com](mailto:mateusz.uchacz@astrazeneca.com)

