ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

Day 2 Breakout Groups Summary Reports

4th ACT Canada Consortium Meeting
Cape Breton
September 26th, 2025

General Structure

- Reminder for presenters
  - Please be seated at the reserved tables by the stage
  - Your group number corresponds to the presentation order
- Presentations have been grouped by theme
  - IDEA Toolkit (Groups 1-4)
  - E21 Guidelines (Groups 5-15)
- After each theme, we invite the audience to use the standing mics for additional discussion

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IDEA Toolkit

Group 01

Pre- Recruitment and Initial Trial Planning

Group 02

Recruitment Stage

Group 03

Trial Execution Stage

Group 04

Analysis and Dissemination of Results

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Group 01

IDEA Toolkit

Pre-Recruitment and Initial Trial Planning

1. *Does the toolkit identify the main barriers and facilitators to inclusive trial planning?*
2. *Is the content in this phase easy to understand and apply in your research setting?*
3. *Are there any critical elements missing?*
4. *How could this section be improved to be more practical or user-friendly?*

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Group 02

IDEA Toolkit

Recruitment Stage

1. *Does the toolkit identify the main barriers and facilitators to inclusive trial planning?*
2. *Is the content in this phase easy to understand and apply in your research setting?*
3. *Are there any critical elements missing?*
4. *How could this section be improved to be more practical or user-friendly?*

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Group 03

IDEA Toolkit

Trial Execution Stage

1. *Does the toolkit identify the main barriers and facilitators to inclusive trial planning?*
2. *Is the content in this phase easy to understand and apply in your research setting?*
3. *Are there any critical elements missing?*
4. *How could this section be improved to be more practical or user-friendly?*

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Group 04

IDEA Toolkit

Analysis and Dissemination of Results

1. *Does the toolkit identify the main barriers and facilitators to inclusive trial planning?*
2. *Is the content in this phase easy to understand and apply in your research setting?*
3. *Are there any critical elements missing?*
4. *How could this section be improved to be more practical or user-friendly?*

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IDEA Toolkit

Pre- Recruitment and Initial Trial Planning	Recruitment Stage	Trial Execution Stage	Analysis and Dissemination of Results

Audience Discussion

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E21 Themes

Groups 05-07

CONTRACEPTION REQUIREMENT/ CHILDBEARING POTENTIAL

Groups 08-11

OB-GYN EXPERTISE IN TRIAL DEVELOPMENT AND IRB INVOLVEMENT

Groups 12-15

ROLE OF SPONSOR IN ENSURING PREGNANT PATIENT DATA IS ADVANCED

Group 05

E21: CONTRACEPTION REQUIREMENT/ CHILDBEARING POTENTIAL

*E21 recommends sponsors recognize and plan for the fact that **pregnancies can occur** when the study population includes individuals of childbearing potential even when rigorous approaches to **mandatory contraception** are implemented.*

- **1.1 Should *mandatory contraception* be required in this case? If yes, what should be the approach if pregnancy occurs despite mandatory contraception?**

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Group 06

E21: CONTRACEPTION REQUIREMENT/ CHILDBEARING POTENTIAL

*E21 recommends sponsors recognize and plan for the fact that **pregnancies can occur** when the study population includes individuals of childbearing potential even when rigorous approaches to **mandatory contraception** are implemented.*

- **1.2 How should results from study participants who were pregnant at some point during the study period be *integrated into analysis* of the study data?**

Group 07

E21: CONTRACEPTION REQUIREMENT/ CHILDBEARING POTENTIAL

*E21 recommends sponsors recognize and plan for the fact that **pregnancies can occur** when the study population includes individuals of childbearing potential even when rigorous approaches to **mandatory contraception** are implemented.*

- **1.3 How should it be determined what data should be collected – and over what timeframe – on *infants born to participants* who were pregnant at some point during the study period?**

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E21: CONTRACEPTION REQUIREMENT/ CHILDBEARING POTENTIAL

Audience Discussion

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Group 08

E21: OB-GYN EXPERTISE IN TRIAL DEVELOPMENT AND IRB INVOLVEMENT

E21 recommends ***early and ongoing engagement with relevant healthcare professionals*** *for protocol development, ethics boards, and safety monitoring. However, experts may not be evenly distributed, raising questions of* ***feasibility and equity****.*

- **2.1 Is a *centralized Canadian hub* more realistic than requirement for OB-GYN expertise for each IRB? Why or why not?**

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Group 09

E21: OB-GYN EXPERTISE IN TRIAL DEVELOPMENT AND IRB INVOLVEMENT

E21 recommends ***early and ongoing engagement with relevant healthcare professionals*** *for protocol development, ethics boards, and safety monitoring. However, experts may not be evenly distributed, raising questions of* ***feasibility and equity****.*

- **2.2 How can we *leverage existing relationships* with industry and in ongoing Canadian obstetric trials to support expertise for trials including pregnant/lactating people?**

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Group 10

E21: OB-GYN EXPERTISE IN TRIAL DEVELOPMENT AND IRB INVOLVEMENT

E21 recommends ***early and ongoing engagement with relevant healthcare professionals*** *for protocol development, ethics boards, and safety monitoring. However, experts may not be evenly distributed, raising questions of* ***feasibility and equity****.*

- **2.3 How to ensure *consistent expertise* at smaller or non-academic trial sites as well as larger academic sites?**

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Group 11

E21: OB-GYN EXPERTISE IN TRIAL DEVELOPMENT AND IRB INVOLVEMENT

*E21 recommends **early and ongoing engagement with relevant healthcare professionals** for protocol development, ethics boards, and safety monitoring. However, experts may not be evenly distributed, raising questions of **feasibility and equity**.*

- **2.4 Are trial personnel, researchers, and IRBs *sufficiently prepared* to safely and ethically include reproductive-aged, pregnant, and breastfeeding individuals in clinical trials? If not, what *strategies or resources* should be implemented to improve training and integrate these considerations into trial design?**

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E21: OB-GYN EXPERTISE IN TRIAL DEVELOPMENT AND IRB INVOLVEMENT

Audience Discussion

Group 12

ROLE OF SPONSOR IN ENSURING PREGNANT PATIENT DATA IS ADVANCED

*E21 suggests that where there is **insufficient** pharmacokinetic (PK) evidence from animal/ human studies, generation of evidence should be **prioritized** in pregnancy and lactation.*

- **3.1 What should be the role/responsibility of the sponsor to *advance evidence generation* in this population even if trial inclusion is not yet deemed safe? (i.e., should PK studied be proposed in tandem with the trial)?**

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Group 13

ROLE OF SPONSOR IN ENSURING PREGNANT PATIENT DATA IS ADVANCED

*E21 suggests that where there is **insufficient** pharmacokinetic (PK) evidence from animal/ human studies, generation of evidence should be **prioritized** in pregnancy and lactation.*

- **3.2 Would a different *study design* be more amenable to earlier inclusion? If so, what design?**

Group 14

ROLE OF SPONSOR IN ENSURING PREGNANT PATIENT DATA IS ADVANCED

*E21 suggests that where there is **insufficient** pharmacokinetic (PK) evidence from animal/ human studies, generation of evidence should be **prioritized** in pregnancy and lactation.*

- **3.3 What incentives can be used to *promote earlier PK studies* for new investigational products?**

Group 15

ROLE OF SPONSOR IN ENSURING PREGNANT PATIENT DATA IS ADVANCED

*E21 suggests that where there is **insufficient** pharmacokinetic (PK) evidence from animal/ human studies, generation of evidence should be **prioritized** in pregnancy and lactation.*

- **3.4 How should we ensure *adequate funding* for additional safety monitoring, testing, and long-term follow-up in trials involving pregnant and lactating participants?**

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E21: ROLE OF SPONSOR IN ENSURING PREGNANT PATIENT DATA IS ADVANCED

Audience Discussion

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Thank you for your participation!