



The PROCEADE- CRC-03 Study

Phase 3 study of premetabart tocentecan with or without bevacizumab compared to trifluridine/tipiracil plus bevacizumab in participants with previously treated metastatic colorectal cancer

Section 1: Synopsis

SoA Arm 1: Precem-TcT Monotherapy

SoA Arm 2: Precem-TcT + Bevacizumab

SoA Arm 2:
Precem-TcT +
Beverizumab

SoA Arm 3: FTD-TPI + Bevacizumab

Section 2: Introduction

Section 3: Objectives and estimands

Section 4: Study design

Section 5: Study population

Section 6: Study intervention(s) + concomitant therapies

Section 7: Discontinuation of intervention/ participant

Section 8: Study assessments and procedures

Section 9: Statistical considerations

Appendices

Appendix 3: Contraception + barrier requirements

Appendix 4: Adverse events: Definitions + procedures

Appendix 5: Clinical laboratory tests

Appendix 6: List of examples of strong and moderate CYP3A4 inhibitors, and strong CYP1A2 inhibitors

Appendix 7: Country / regional requirements

Appendix 8: RECIST Version 1.1

Appendix 9: Protocol amendment history



PROCEADE-MP-EnP

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