DEVELOPMENT OF A COLLABORATIVE APPROACH TO ACCRUAL OF ADOLESCENTS AND YOUNG ADULTS WITH CANCER TO CLINICAL TRIALS IN CANADA:
A JOINT REPORT FROM THE PEDIATRIC C17 COUNCIL AND THE ADULT CANADIAN CANCER TRIALS GROUP

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ABSTRACT
Adolescents and young adults (AYA; age 15–29 years) with cancer are at risk for lower accrual and compliance compared to pediatric and adult populations. This may be related to their low participation in cancer clinical trials; increasing accrual to these trials has become a priority for closing this “AYA gap.”

BACKGROUND
Over the past 30 years, adolescents and young adults (AYA, 15–29 years of age) with cancer have shown significantly less improvement in survival than younger and older patients. Evidence suggests this may be related to their low participation in cancer clinical trials; increasing accrual to these trials has become a priority for closing this “AYA gap.” (Payer Off and Sekeres M. 2018).

METHODS
Facilitated by:
• US National Clinical Trials Network (NCTN) grant trial
• Partnership between the adult Canadian Cancer Trials Group (CCTG) and C17, the Children’s Oncology Group Canadian Senior Medical Office.

Issues to address:
• Communications
• Clinical Trial Application process
• Contracts with sites and partners
• Research Ethics Board approvals
• Informed consent and assent
• Safety reporting
• Qualified Investigator roles at pediatric and adult sites
• Site activation
• Registration & Randomization procedures / Credentialing accrual
• Training
• Creation of a clinical trial website

PROGRESS
• Single sponsor (CCTG) with a single Clinical Trial Application (CTA) to Health Canada.
• First trial activated in Canada using this platform: COG ARST1321 Phase II/III pazopanib neoadjuvant trial in patients with non-rhabdomyosarcoma soft tissue sarcoma.
• Twelve centres have opened the study: seven pediatric and five adult.
• Good collaboration and communication across CCTG, C17 and the participating sites has been essential.

Informed Consent and Assent
Informed Consent and Assent templates obtained from COG. CCTG and C17 added key elements required for Canadian participation, including:
1. Identification of Canadian sponsor.
2. Incorporation of The Subject’s Responsibilities Section to the consents to comply with GCP section 4.8.10 (e).
3. Addition of possible risks and side effects related to pazopanib on the basis of Canadian sponsor medical review of the latest Investigators Brochure/Product Monograph (IB/PM).
4. Inclusion of detail necessary to reproductive risks.
5. Modification of the list of organizations that may inspect participant records.

CONCLUSIONS
• The AYA platform was developed to enable Canadian institutions to participate in clinical trials that span across the pediatric-adolescent-adult age range, while maintaining compliance with Canadian regulations.
• The development of a national standardized approach to clinical trial accrual and compliance will facilitate future trials for AYAs.