# CYP-C
# National Data Applications

March 10, 2017

# Introduction to CRF's and Data Dictionary

By Emilie Martineau CYP-C CRA and CRA Management representative

# 1.0 Registration

- Demographics
- Age at diagnosis is pre-populated based on DOB.
- Ethnicity: specify all that apply (mother and father ethnicity)

# 2.0 Diagnostic Information

- Time to treatment (route to get diagnosis)
- Diagnosis based on ICDO-3 M and T code
- Pre-populated ICCC code
- Staging and risk
- Information on ALL-AML and MDS including type, chromosomal information
- Metastasis (general sites)

## 3.0 Patient Contact and Status

## 4.0 Height and Weight

- Yearly follow-ups for 5 years (extended to 66 months maximum)
- If patient died outside of 66 months of F-U, section 15.0 to capture date of death.

# 5.0 Protocol/Treatment Plan

- Registered or not with the reason for not reg.
- Following a COG or other group protocol.
- Progressive/refractory disease.
- Include start and end date of therapy.
- Multiple treatment plans

CHILDREN'S ONCOLOGY GROUP

DANA-FARBER CANCER INSTITUTE

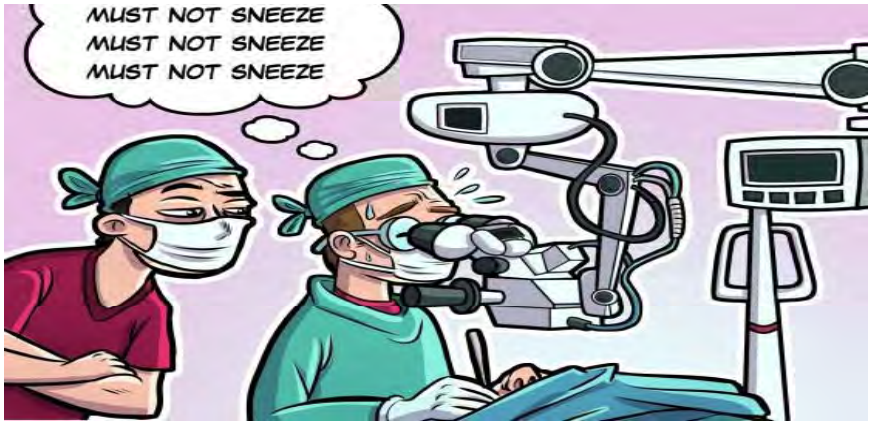
Pediatric Brain Tumor Consortium

# 6.0 Chemotherapy List
# 7.0 Chemotherapy Details

- If agents not in the list, other.
- Details for some agents like anthracyclins.
- Date agent first and last administered.

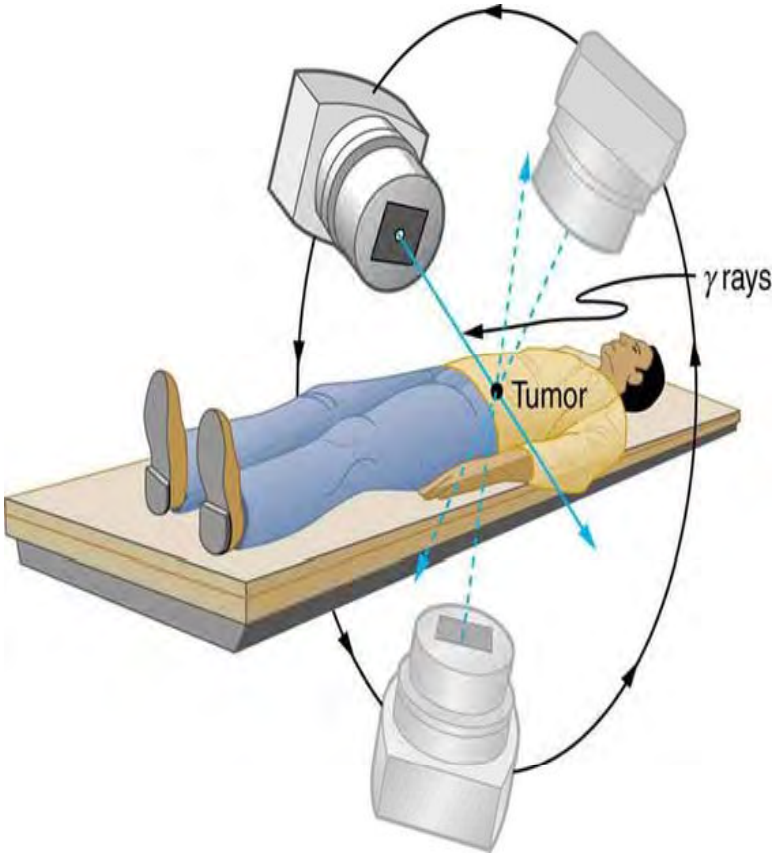
# 8.0 Surgery Details

- Only cancer related
- Secondary surgeries such as shunt insertions, amputation
- Central lines insertion not captured



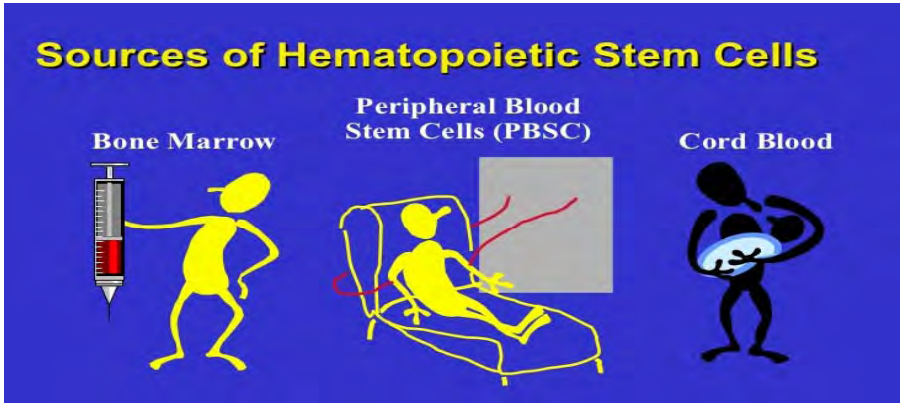
# 9.0 Radiation Details

- Start and end date
- Intent
- Systemic therapy capture here
- Radiation site(s) is general
- Boost



# 10.0 Hematopoeitic Cell Transplantation

- Date of transplant
- Type/match/mismatch
- Radiation details
- Chemotherapy details
- Some agents not in the list (see section 6.0)



# 11.0 Hospitalisations

- Dates can be estimated if we're missing information
- Reasons for admission are A. Cancer related and/or complications C. HCT related D. Non-cancer related E. N/A or unknown



## 12.0 Complications

- Before Jan 1, 2011: CTCAE-3
- After Jan 1, 2011: CTCAE-4
- HCT complications

## 13.0 Relapse

- If the child achieved COMPLETE response
- Includes dates, metastasis

## 14.0 Other Therapy

- Laser therapy for retinoblastoma
- Donor leukocyte infusion
- Medicine man or other non conventionnal therapy

## 15.0 Death

- Date
- Cause

# Thank you!

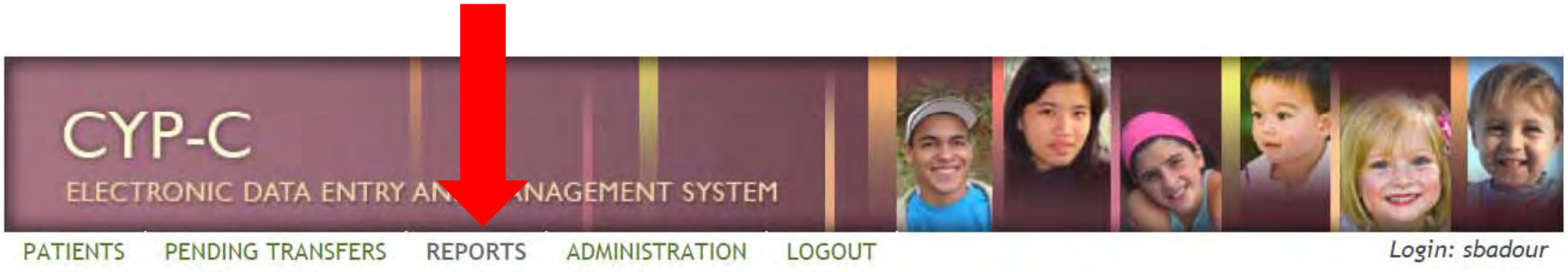
# How to Generate and Export Reports in eCYP

CYP-C Champions Webinar

10-Mar-17

Stephanie Badour, CCRP

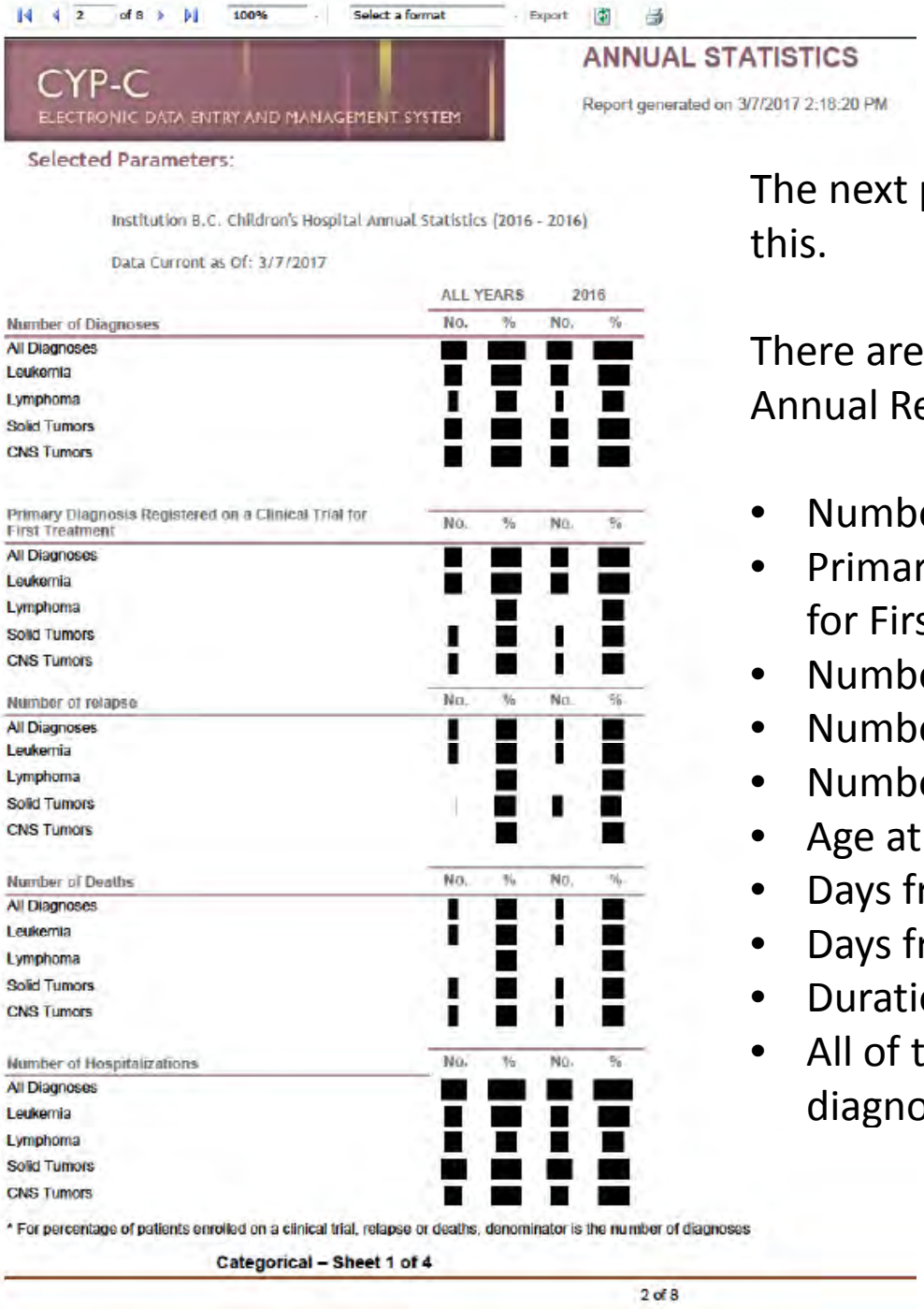
BC Children's Hospital




- Log into eCYP on EXPLORER (not Chrome)
- Click on “Reports” Tab
- Choose which report you would like to generate
- For this example, I am choosing “Annual Statistics”

Select your parameters according to what you would like to know.

The report will open in a separate window (ensure pop-ups are disabled on your browser).
Sometimes the first page does not display the data, but you need to click on the next page of the report by clicking on the blue arrow.



2 of 8 100% Select a format Export

CYP-C
ELECTRONIC DATA ENTRY AND MANAGEMENT SYSTEM

ANNUAL STATISTICS

Report generated on 3/7/2017 2:18:20 PM

Selected Parameters:

Institution B.C. Children's Hospital Annual Statistics (2016 - 2016)

Data Current as Of: 3/7/2017

| | ALL YEARS | | 2016 | |
|---|---|---|---|---|
| Number of Diagnoses | No. | % | No. | % |
| All Diagnoses | | | | |
| Leukemia | | | | |
| Lymphoma | | | | |
| Solid Tumors | | | | |
| CNS Tumors | | | | |

| Primary Diagnosis Registered on a Clinical Trial for First Treatment | No. | % | No. | % |
|---|---|---|---|---|
| All Diagnoses | | | | |
| Leukemia | | | | |
| Lymphoma | | | | |
| Solid Tumors | | | | |
| CNS Tumors | | | | |

| Number of relapse | No. | % | No. | % |
|---|---|---|---|---|
| All Diagnoses | | | | |
| Leukemia | | | | |
| Lymphoma | | | | |
| Solid Tumors | | | | |
| CNS Tumors | | | | |

| Number of Deaths | No. | % | No. | % |
|---|---|---|---|---|
| All Diagnoses | | | | |
| Leukemia | | | | |
| Lymphoma | | | | |
| Solid Tumors | | | | |
| CNS Tumors | | | | |

| Number of Hospitalizations | No. | % | No. | % |
|---|---|---|---|---|
| All Diagnoses | | | | |
| Leukemia | | | | |
| Lymphoma | | | | |
| Solid Tumors | | | | |
| CNS Tumors | | | | |

* For percentage of patients enrolled on a clinical trial, relapse or deaths, denominator is the number of diagnoses

Categorical – Sheet 1 of 4

2 of 8

The next page of the report will look something like this.

There are a number of fields generated in the Annual Report.

- Number of Diagnoses (general groupings)
- Primary Diagnosis Registered on a Clinical Trial for First Treatment
- Number of Relapses
- Number of Deaths
- Number of Hospitalizations
- Age at Diagnosis
- Days from Initial Symptoms to Diagnosis
- Days from Diagnosis to Treatment
- Duration of Hospitalization
- All of the above broken down into their specific diagnoses

# General CYP-C data dump

- Coming soon!
- Possible to work with your IT departments and Dapasoft to generate a data dump of all CYP-C data (not limited to Report parameters)
- Dependent on your IT department's availability and prioritization of projects
- Likely to work in a similar manner to generation and exporting of Reports data

# Limitations of data

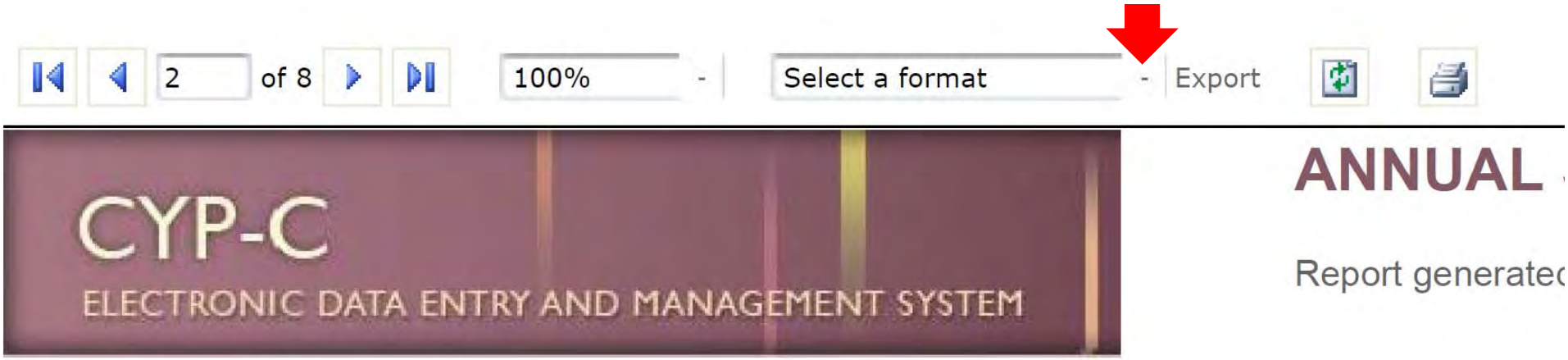
- Before creating a data query or generating a report, know the limits of the data
- Read through the CYP-C data dictionary very thoroughly to know HOW the data was collected and under what parameters/definitions so you can understand what the data report is truly capturing

Example- Query for “Time from Diagnosis to Treatment”

- The only chemotherapy data collected under CYP-C is the chemotherapy that requires collection of cumulative dose information (ex. Anthracyclines). General protocol therapy is only captured by the protocol name under the Treatment Plan.
- This is important to know if you would like to query, “Time from Diagnosis to Treatment Start” for Leukemias, because generally this would be dictated by time from initial diagnostic procedure (BM LP) to time of systemic chemo start, however Vincristine or steroid start dates are not collected by CYP-C, so you need to use another parameter.

- Another example would be to know what is considered “Start of Protocol Treatment” date per diagnosis
- Start of Protocol Treatment can also mean surgery for CYP-C purposes, which is not what we would normally consider for queries, as we would use the start of systemic chemotherapy instead

# Exporting CYP-C Report Data




## Selected Parameters:

- Select from the Dropdown list the type of file to export.

Formats available for Export:

- XML File with report data
- CSV (Comma delimited)
- PDF
- MHTML (web archive)
- Excel
- Tiff file
- Word

- Click Export

- Save file in a safe and secure location with a password per Good Clinical Practice, especially if any patient identifiers are involved in the report

# Importing CYP-C Report Data

# Microsoft Access

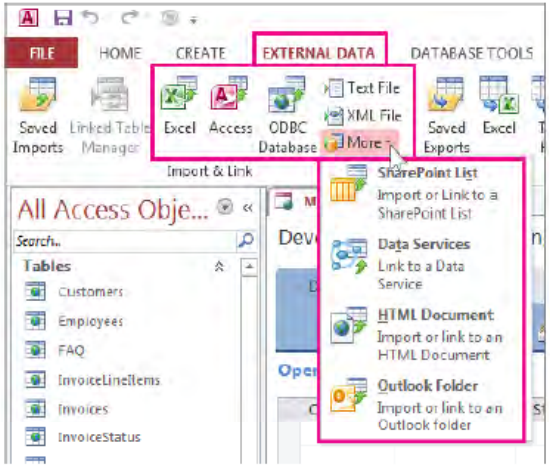
## Importing into a desktop database

Access desktop databases can import a few more types of files than apps. If you have a file type that you can't import directly into an app, you might be able to import it into a desktop database first, and then import the desktop database table(s) into the app.

Desktop databases also let you append external data to an existing table, a feature unavailable in apps.

To import data into a desktop database:

1. On the **External Data** tab, in the **Import & Link** group, click the type of the file you want to import.




2. Follow the instructions in the **Get External Data** wizard.

# External data operations available in apps and desktop databases

This table gives you a quick reference of which kinds of files you can import or link to Access apps or desktop databases.

| | Access apps can import... | Access apps can link to... | Desktop databases can import... | Desktop databases can link to... |
|---|---|---|---|---|
| Microsoft Excel | ■ | | ■ | ■ (read-only) |
| Microsoft Access | ■ | | ■ | ■ |
| ODBC Databases, such as SQL Server | ■ | | ■ | ■ |
| Text or comma-separated value (CSV) files | ■ | | ■ | ■ (add new records only) |
| SharePoint List | ■ | ■ (read-only) | ■ | ■ |
| XML | | | ■ | |
| Data Services | | | ■ | ■ (read-only) |
| HTML Document | | | ■ | ■ |
| Outlook folder | | | ■ | ■ |

Microsoft Access

# SPSS Software

- SPSS is a user-friendly program that facilitates data management and statistical analyses. It is free to use.
- It can perform highly complex data manipulation and analysis with simple instructions
- Excel or CSV data files can be imported into SPSS
- Tutorials on Importing Data into SPSS can be found here:

http://libguides.library.kent.edu/SPSS/ImportData

- Tutorials on using SPSS are also offered in various formats online

# CYP-C
# National Data Applications

CANCER IN YOUNG PEOPLE IN CANADA PROGRAM

PROGRAMME CANCER CHEZ LES JEUNES AU CANADA

March 10, 2017

# The Process

1. CYP-C Management Committee
2. Pediatric Oncology Group of Ontario (POGO)
3. Public Health Agency of Canada (PHAC)

- Applications reviewed in order received

# The Process – CYP-C

1. CYP-C Management Committee

- duplication, feasibility, validity, relevance and timeline of project
- Justification of elements to avoid delays later. Is the element necessary? Is a full date necessary? Is justification adequately detailed?
- Data protection and data linkages.

# The Process- POGO

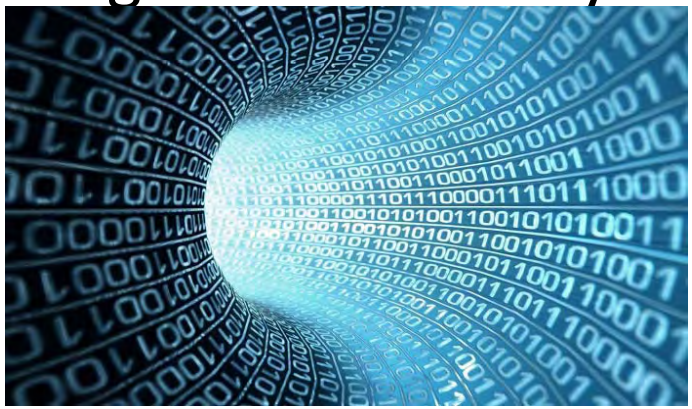
2. POGO

- CYP-C collects data directly from the non-Ontario centres. A data sharing agreement with POGO allows them 15 business days to review all applications.
- They may veto release of Ontario data.
- DO NOT apply to CYP-C and request Ontario only data.

# The Process - PHAC

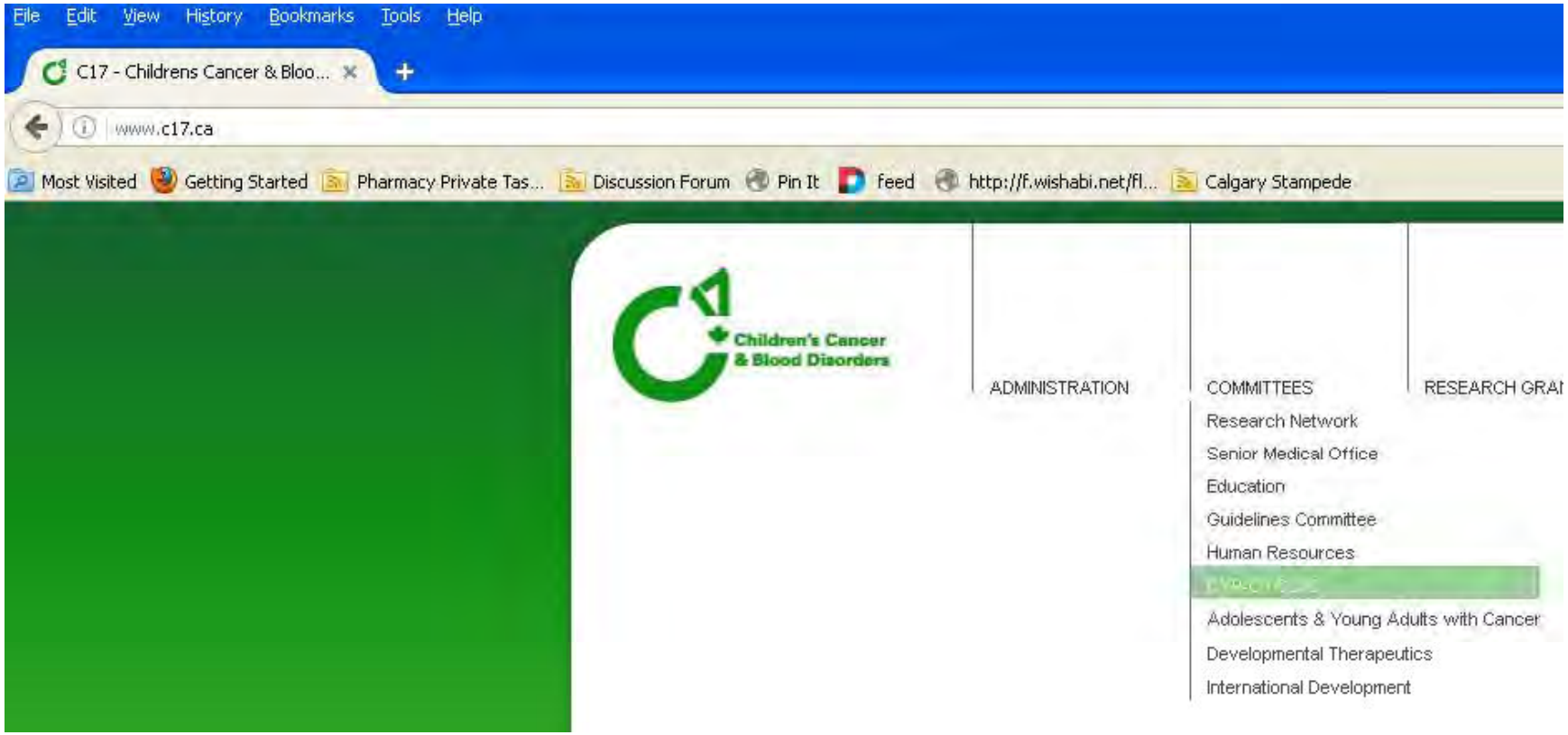
3. PHAC – Privacy and document review

- Institutional REB approval (& full application)
- Signed Data Confidentiality agreement
- Signed Form 8(2)(j) of the Privacy Act
- Other (ex. aboriginal community engagement)

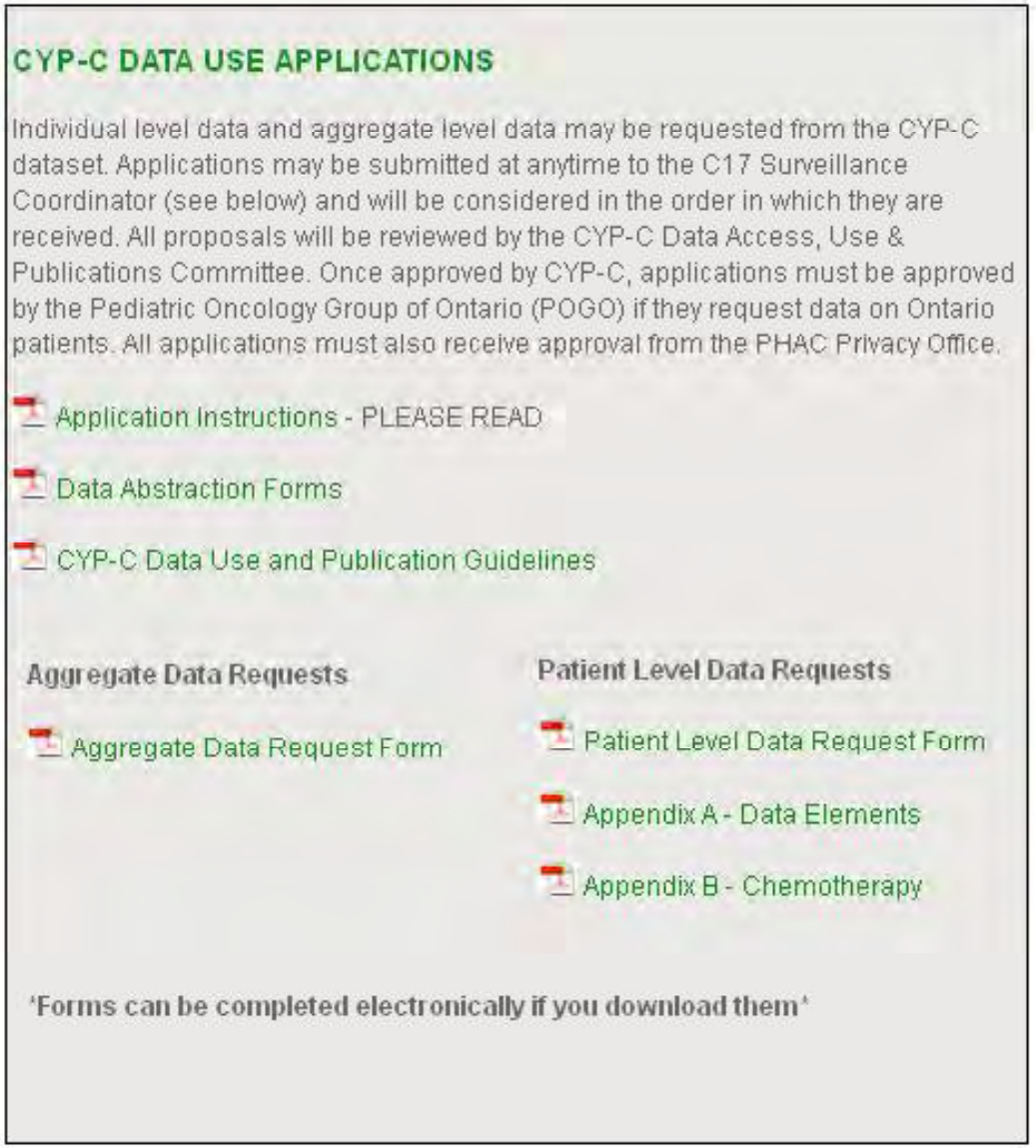


- PHAC cuts the dataset and contacts researcher to transfer data.

# Where to go – www.C17.ca



# Where to go – www.C17.ca



**CYP-C DATA USE APPLICATIONS**

Individual level data and aggregate level data may be requested from the CYP-C dataset. Applications may be submitted at anytime to the C17 Surveillance Coordinator (see below) and will be considered in the order in which they are received. All proposals will be reviewed by the CYP-C Data Access, Use & Publications Committee. Once approved by CYP-C, applications must be approved by the Pediatric Oncology Group of Ontario (POGO) if they request data on Ontario patients. All applications must also receive approval from the PHAC Privacy Office.

Application Instructions - PLEASE READ

Data Abstraction Forms

CYP-C Data Use and Publication Guidelines

**Aggregate Data Requests**

Aggregate Data Request Form

**Patient Level Data Requests**

Patient Level Data Request Form

Appendix A - Data Elements

Appendix B - Chemotherapy

**'Forms can be completed electronically if you download them'**

CANCER IN YOUNG PEOPLE IN CANADA PROGRAM
PROGRAMME CANCER CHEZ LES JEUNES AU CANADA

## Patient Level Data Access Requests

Cancer in Young People in Canada/ Cancer Chez les Jeunes au Canada program (CYP-C /CCJC)

# Application Tips

- Read instructions!
- Carefully consider who needs access to patient level data
- Is multi-site collaboration possible?
- Attach additional pages as necessary and/or separate protocol
- Justify each element and add a narrative for PHAC Privacy
- Ensure adequate security
- If linking with other databases, is there a risk of re-identification?

# Appendix A - Data Element Checklist

Indicate requested data elements → Shaded elements not available for Ontario patients.

Principal Investigator:

Project Title:

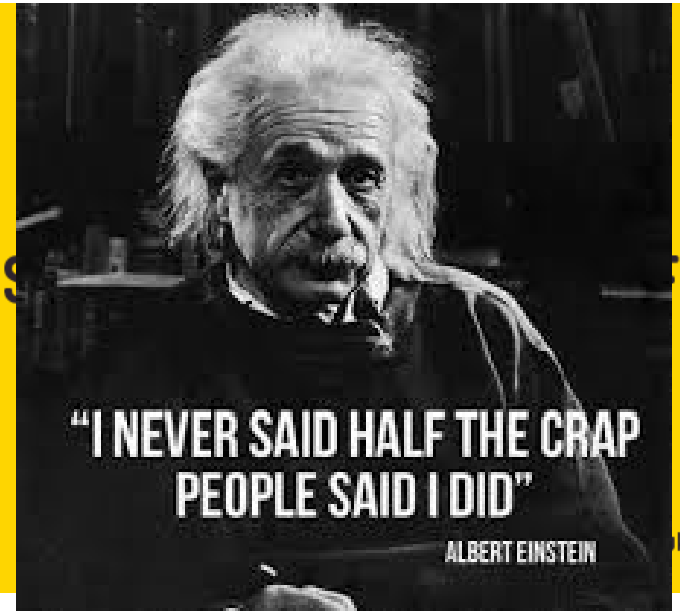
| | |
|---|---|
| Diagnoses requested: | |
| Years requested (specify if years relate to diagnosis or other event such as relapse or death): | |
| Geographic regions requested: | |
| Other eligibility criteria: | |

| | | | CYP-C USE ONLY | | |
|---|---|---|---|---|---|
| A - Merged data requested. Not available for all elements (as indicated). | | | 1. Approved for release | | |
| B - Separate CYP-C and POGO requested. Only CYP-C available for shaded. | | | 2. REB approved | | |
| A | B | | 3. Included in data cut | | |
| **1.0 Registration** | | | 1 | 2 | 3 |
| ☐ | ☐ | 1.4 Sex | ☐ | ☐ | ☐ |
| ☐ | ☐ | 1.5 Birth Date Day ☐ Month ☐ Year ☐ | ☐ | ☐ | ☐ |
| ☐ | ☐ | 1.6 Age at diagnosis | ☐ | ☐ | ☐ |
| ☐ | ☐ | 1.7 Province of residence at time of diagnosis | ☐ | ☐ | ☐ |
| ☐ | ☐ | 1.9 Postal code of residence at diagnosis First 3 digits ◯ Full ◯ | ☐ | ☐ | ☐ |
| ☐ | ☐ | 1.10 Race(s) | ☐ | ☐ | ☐ |
| **2.0 Diagnostic Information** | | | | | |
| **2.1 Time to Treatment** | | | | | |
| | ☐ | 2.1.1 Date of first health care contact Day ☐ Month ☐ Year ☐ | ☐ | ☐ | ☐ |
| ☐ | ☐ | 2.1.2 Health care professional contacted | ☐ | ☐ | ☐ |
| | ☐ | 2.1.3 Date if alternate health care contact Day ☐ Month ☐ Year ☐ | ☐ | ☐ | ☐ |
| | ☐ | 2.1.4 Alternate health care professional contacted | ☐ | ☐ | ☐ |
| | ☐ | 2.1.5 Date first seen by oncologist Day ☐ Month ☐ Year ☐ | ☐ | ☐ | ☐ |
| | ☐ | 2.1.6 Type of oncologist | ☐ | ☐ | ☐ |
| | ☐ | 2.1.7 Institution of oncologist | ☐ | ☐ | ☐ |
| | ☐ | 2.1.8 Date first seen by surgeon Day ☐ Month ☐ Year ☐ | ☐ | ☐ | ☐ |

# Appendix B -Chemotherapy List

| Chemotherapeutic Agent | Administered (6.2) | | Cumulative (7.1) | |
|---|---|---|---|---|
| | CYP-C | POGO | CYP-C | POGO |
| 17-AAG, demethoxygeldanamycin | | | | |
| Alemtuzumab, Campath | | | | |
| Alisertib (MLN8237) | | | | |
| Aminocamptothecin (9-AC, 9-aminocamptothecin) | | | | |
| Amifostine | | | | |
| Amsacrine, Acridinyl anisidide, m-AMSA | | | | |
| Antilymphocyte globulin (ALG)/ Antithymocyte globulin (ATG/ATGAM) | | | | |
| Anti-rejection drugs (Sirolimus, Tacrolimus, MMF) | | | | |
| Arsenic trioxide (Trisinox) | | | | |
| Asparaginase E-Coli (L-Asp), Elspar, Kidrolase | | | | |
| Asparaginase Erwinia (Erwinase) | | | | |
| Asparaginase Peg | | | | |
| Azacytidine (Aza-C) 5-AZA, 5-AC, 5-azacytidine) | | | | |
| Bcl-2 antisense, Oblimersen, Genasense, Augmerosen | | | | |
| Bevacizumab (Avastin) | | | | |
| Bleomycin, Blenoxane, Bleo | | | | |

# Summary




- Background, instructions and forms found on the C17 website
- 3 levels of review: CYP-C, POGO & PHAC
- Be prepared to justify and explain individual data elements and study design
- Contact randy.barber@ahs.ca with applications or any questions