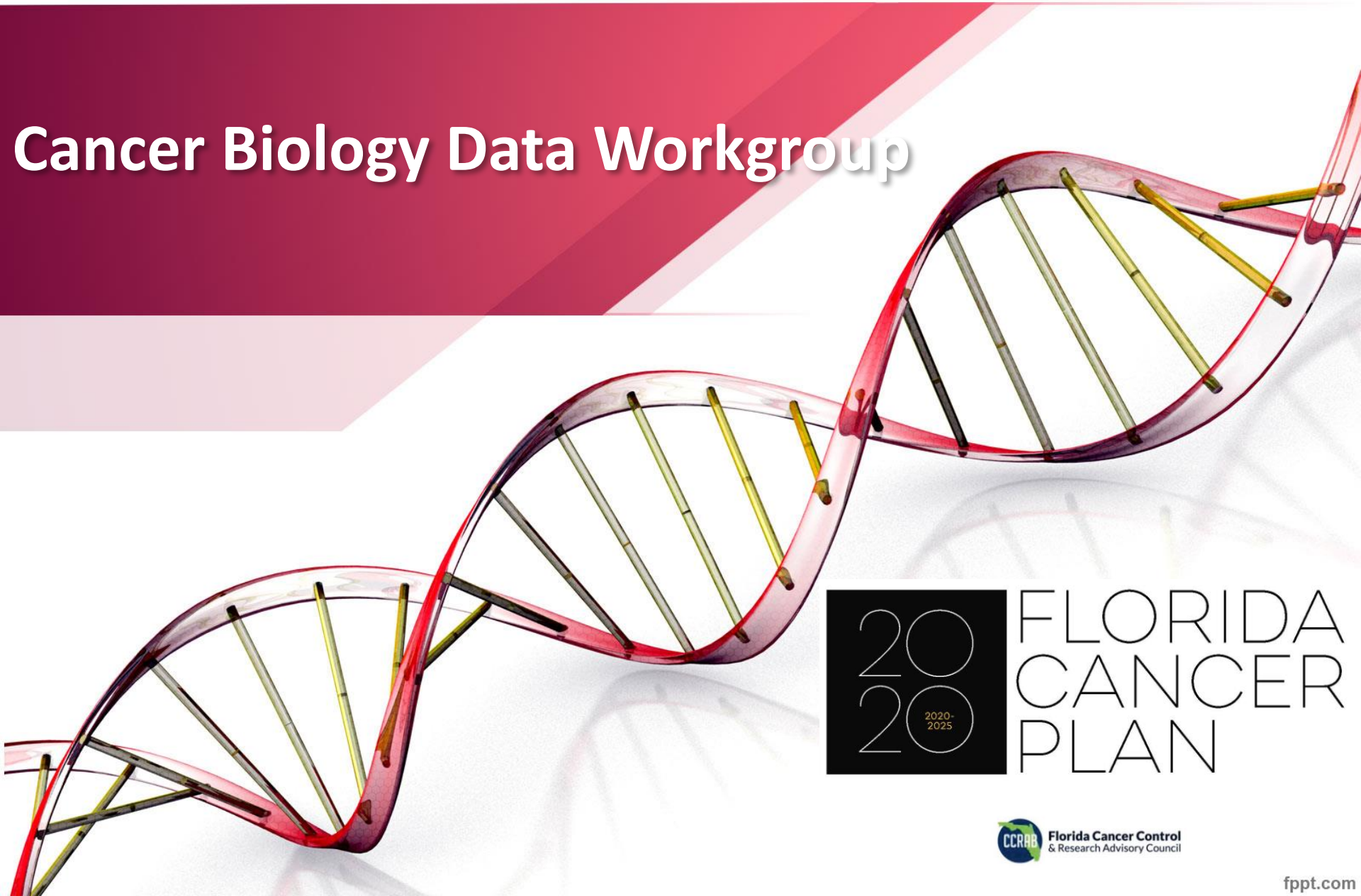
Cancer Biology Data Workgroup



2020-2025 FLORIDA CANCER PLAN

Florida Cancer Control & Research Advisory Council

Overall Objective

Objective 2.2

By 2025, pilot the addition of cancer biology data such as somatic gene mutations or National Cancer Institute/North American Association of Central Cancer Registries defined site-specific data items as data collected and archived by Florida's statewide cancer data and surveillance program.

OPPORTUNITIES:
Why Collect Cancer Biology Data

- Influence of genomic testing on cancer survival and quality of life; reasons to expand insurance coverage for testing.
- Identify disparities of access to genetic testing, by demographics, geography, and socio-economic status.
- Cost/Benefit analysis of testing all cancers.
- By linking to registry data, retrospective analysis of genetic testing outcomes to inform treatment effectiveness.

CHALLENGES

- No cancer registry in the country has implemented comprehensive population-based collection of genetic data. The Kentucky Cancer Registry has begun this process and plan to collaborate with them on pilot.

- Reasons for this are varied:
  - Cost
  - Complexity
  - Non-standard reporting of results
  - Rapidly evolving and expanding field of genetic testing

CHALLENGES:
Legislation Review

FS 760.40 – Genetic Testing; definitions; express consent required; confidentiality; notice of use of results

FS 817.5655 Unlawful Use of DNA

- Does this legislation apply to public health and cancer surveillance?
- Are there any barriers stopping the pilot from proceeding?
- Who should be engaged to determine if this is a barrier to reporting to the FCDS?

FS 395 and Rule 64D – Current Registry Legislation

- Does current legislation need review?

Pilot Option 1 – Abstracting

- Manual Abstracting by Registrars
  - Higher burden on registrar
  - Lack of training on reading Next Generation Sequencing (NGS) reports
  - Smaller Institutions/Providers may not have resources
  - Information may or may not be found in medical chart
  - Limited number of tests defined in national dataset
  - Adding new tests nationally not flexible and takes time
  - Impact on software vendors
- **Decision: Not sustainable at a population level**

Pilot Option 2 – Automation

- Import Directly from NGS Reports
  - No burden on registrar or additional training
  - All available tests can be collected
  - Easily add new tests as they become available
  - Multiple Formats – One or more selected
    - XML/JSON/VCF – Allows for discreet result coding and patient linkage
    - PDF Clinical Reports – Support for QC; no discreet result coding
    - BAM File – Raw Data (~2GB per report)
      - May allow for consistency in mutation results reported
      - Allows for ability to retrieve mutations that become significant in future
  - Obtaining test results from NGS Labs is more efficient
- **Decision: Sustainable at a population level (Selected)**

Pilot Scope – Reporters

- Selection based on reporters that do NGS
  - Academic Centers/Centers of Excellence
  - Florida Cancer Specialists (FCS)
  - One or two reference labs
    - Foundation Medicine
    - Caris Life Sciences
    - Guardant Health
    - Tempus

Pilot Scope – Cancer Sites/Tests

- Cancer Site Selection
  - Consider Cancer Sites which benefit from NGS
  - Limit selection to one or two cancer sites
  - Lung was initially suggested
- Gene Assays/Tests Selection
  - Hundreds of NGS tests to choose from
  - Limit numbers collected for feasibility of pilot
  - Determine how results are coded

Pilot Scope – Selection Approach

- Develop survey asking:
  - Which cancer sites are getting NGS
  - What gene assays/tests are being collected
  - How are results being coded
- Send Survey to Academic Centers/FCS
- Analyze and look for overlap between facilities
- Select common cancer sites and tests to collect

What's Next

- Develop detailed workplan
  - Develop survey/analyze/select
    - Cancer Sites and Tests
    - Volunteer reporters
  - Define collection methodology
  - Define metrics to monitor pilot
  - Determine funding/resources requirements
- Submit workplan and budget to CCRAB
  - Secure funding
- Implement Pilot

Projected Pilot Resources

- Hardware
- Software – Collection and Registry Integration
- Cloud Storage – If BAM files are desired
- Expert Consultant/Contractor in Genetic Testing
- Staffing – Day to Day processing

Post Successful Pilot

- Develop workplan to transition to population-based data collection
- Identify or develop reporting data standard
- Determine annual funding to sustain collection
- Develop data governance and data dissemination policies
- Submit workplan and budget to CCRAB

Closing Thoughts

- Collecting cancer biology data is very complicated
- Lack of reporting standards
  - No Standards for reporting
  - Discordant results even within same report
- Significant infrastructure will be required
- Expertise needed for data collection and dissemination
- Staffing - Visual review of reports and quality control as needed

The Amazing WG Membership

Co-Chair – Dr. Michael Diaz – FCS, CCRAB and Gary Levin - FCDS

- Dr. Clement Gwede – Moffitt, CCRAB
- Dr. Erin Kobetz – UM/SCCC, CCRAB
- Dr. Bobbie McKee – Moffitt, CCRAB
- Dr. David Lee – UM/SCCC, FCDS
- Dr. Monique Hernandez – FCDS
- Megan Wessel – ACS, CCRAB
- Trevor Heritage - FCS
- Dr. Dana Rollison - Moffitt
- Dr. Petr Starostik – UF Health
- Dr. Eric Padron – Moffitt
- Dr. Luis Raez - Memorial
- Stuart Herna – UM/SCCC
- Phillip Reisman – Moffitt
- Jiang Bian – UF/One Florida

THANK YOU