Finding Cancer Trials Collaborative

Identifying Approaches to Making Cancer Clinical Trials Easier to Find

NIH NATIONAL CANCER INSTITUTE

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Agenda

1. Challenge: Finding Cancer Clinical Trials is Complex
2. Background on NCI's Clinical Trials Reporting Program (CTRP)
3. Finding Cancer Trials Collaborative Activities

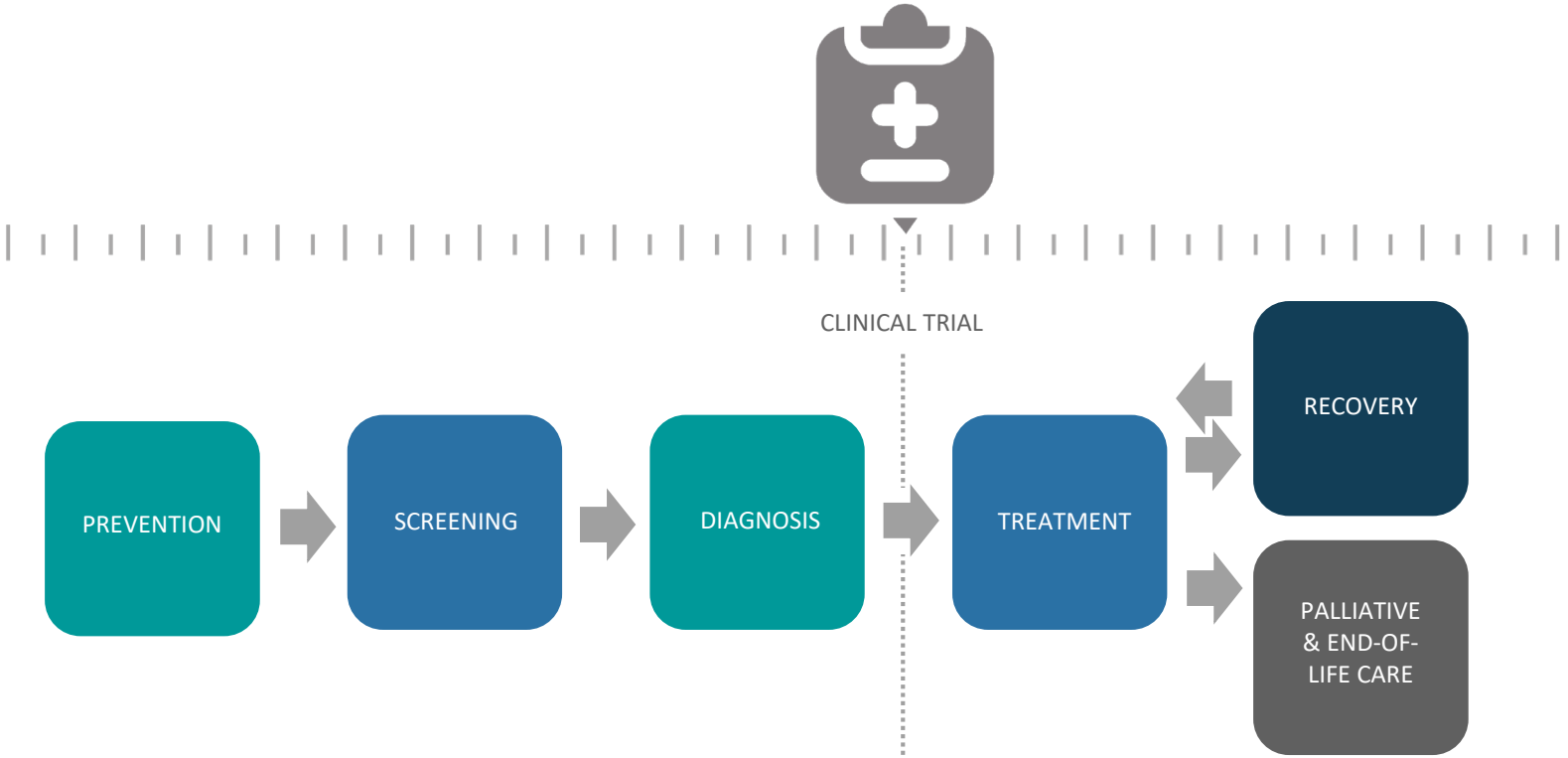
Challenge: Finding Cancer Clinical Trials is Complex

Challenge: Finding Cancer Clinical Trials is Complex

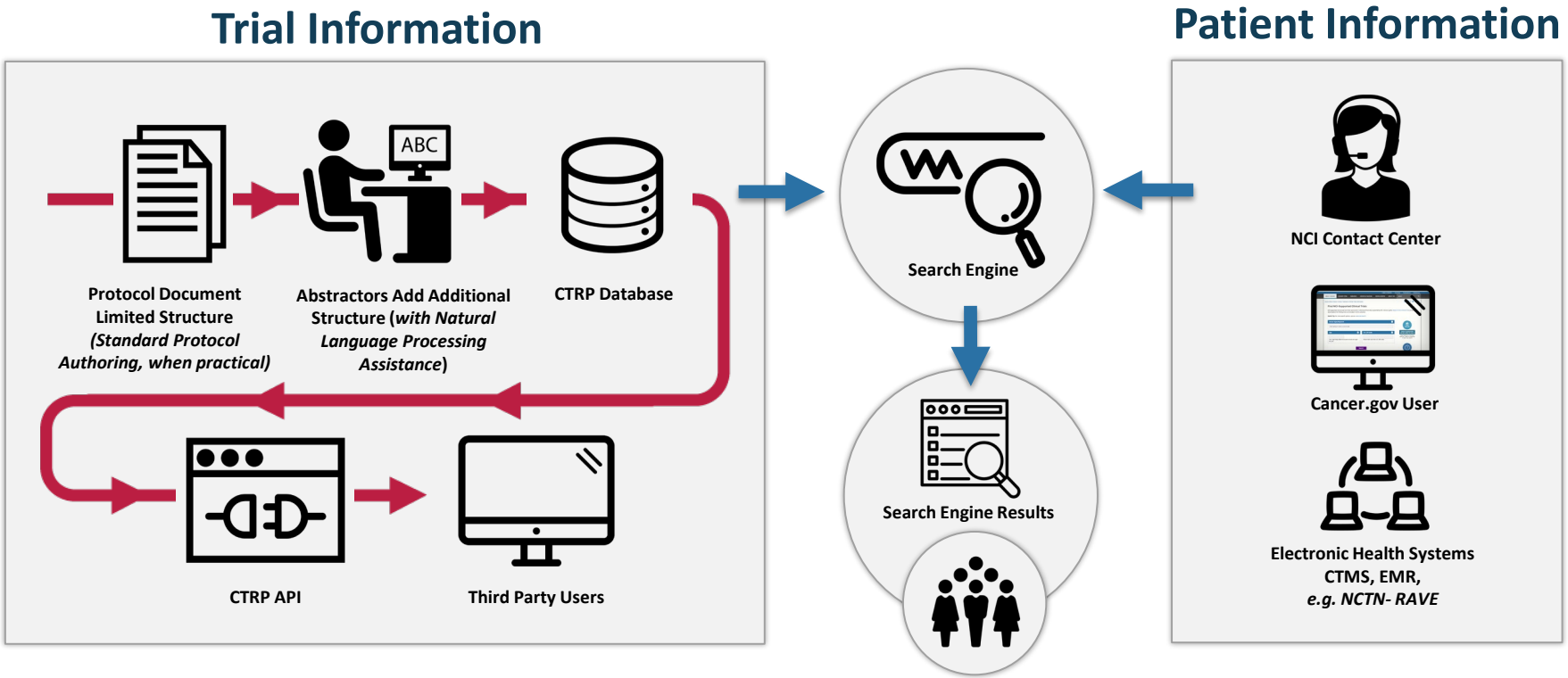
- Patients and providers have:
  - Common needs
  - Different search techniques
- Multiple sources for information
- Searches retrieve too many trials for which a patient is ineligible
- List of clinical trials returned is not sufficiently precise

"…Patients should be able to seamlessly find a clinical trial that might suit a specific condition. Doctors should have an easy way of guiding patients through the process…"
Cancer Moonshot Summit, 2016

Finding Cancer Trials: Vision



NCI Cancer Clinical Trials Search – Multiple Interrelated Parts



Background - CTRP

What is NCI's Clinical Trials Reporting Program (CTRP)?

- Database contains **regularly updated information** on all NCI-supported interventional trials
- Utilizes **standardized data elements** and consistent protocol abstraction
- Supports NCI clinical trials **portfolio management**
- Supports **registration and results reporting** to ClinicalTrials.gov
- Source of data for NCI's clinical trials search tool

Why is CTRP unique?

- **Consistent terminology** and **standardized** data elements
- Quarterly reporting of accrual
- **Standard representation** of persons and **organizations**
- Inclusion of structured biomarker information
- Identification of associated NCI awards and contracts
- **Regular updates**

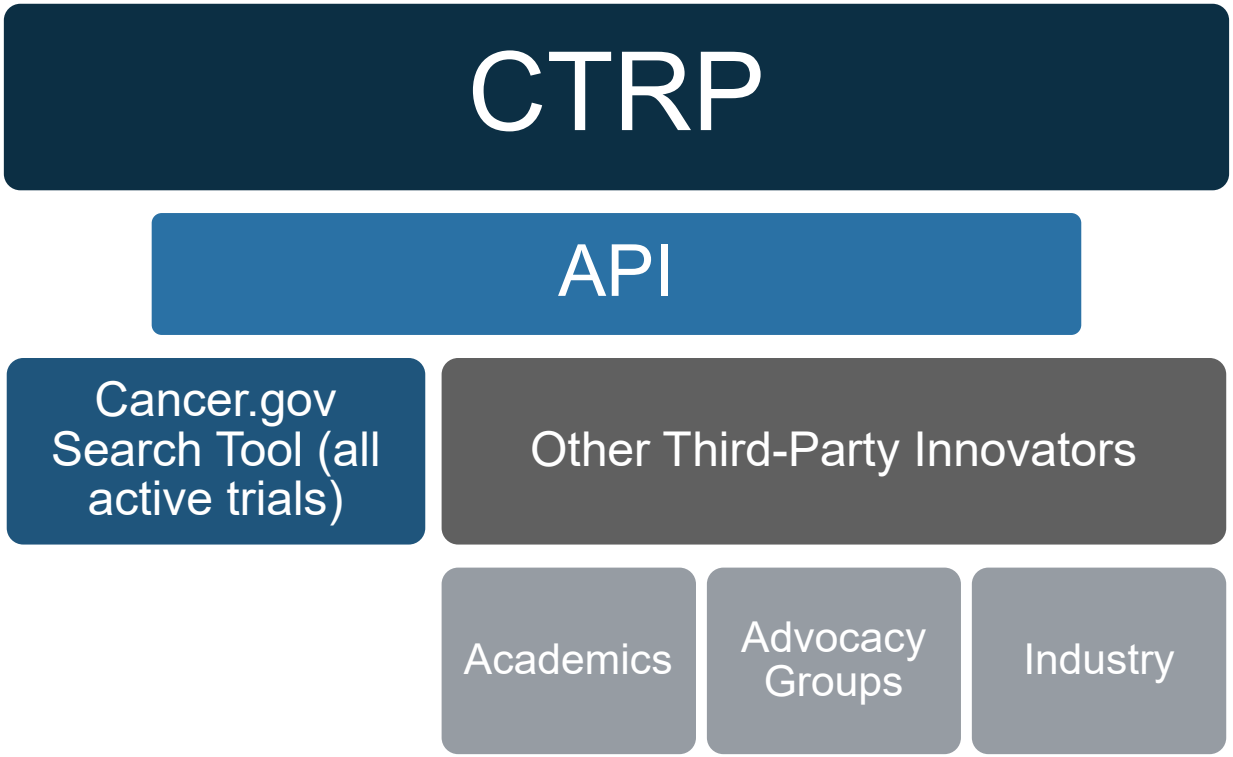
Trials Included in NCI's CTRP

Approximately **90%** of interventional cancer clinical trials open to patient accrual in the United States found in ClinicalTrials.gov are also in CTRP*

- Interventional clinical trials taking place in at least one NCI-designated cancer center, including industrial trials
- Trials sponsored by NCI, as well as trials sponsored by other entities
- Reporting of observational and ancillary/correlative studies is optional

*as of September 2018

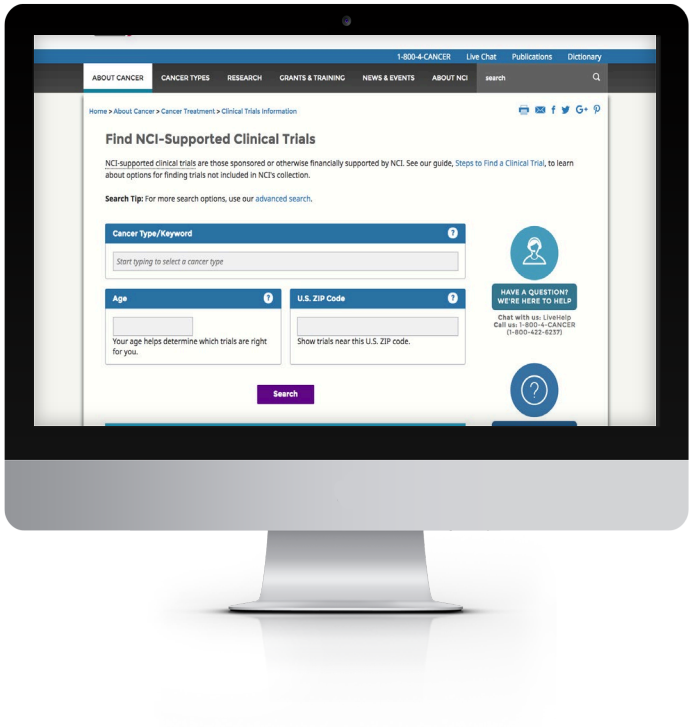
Application Programming Interface (API)



Finding Cancer Trials Collaborative Updates

Cancer Clinical Trials Search on Cancer.gov

- 2017, transitioned to CTRP as the data source for Cancer.gov search
- Recent enhancements include:
  - Chat-box help
  - Integration with NCI's Thesaurus and Enterprise Vocabulary Services to improve search accuracy
  - Type-ahead and multi-select options to improve user experience



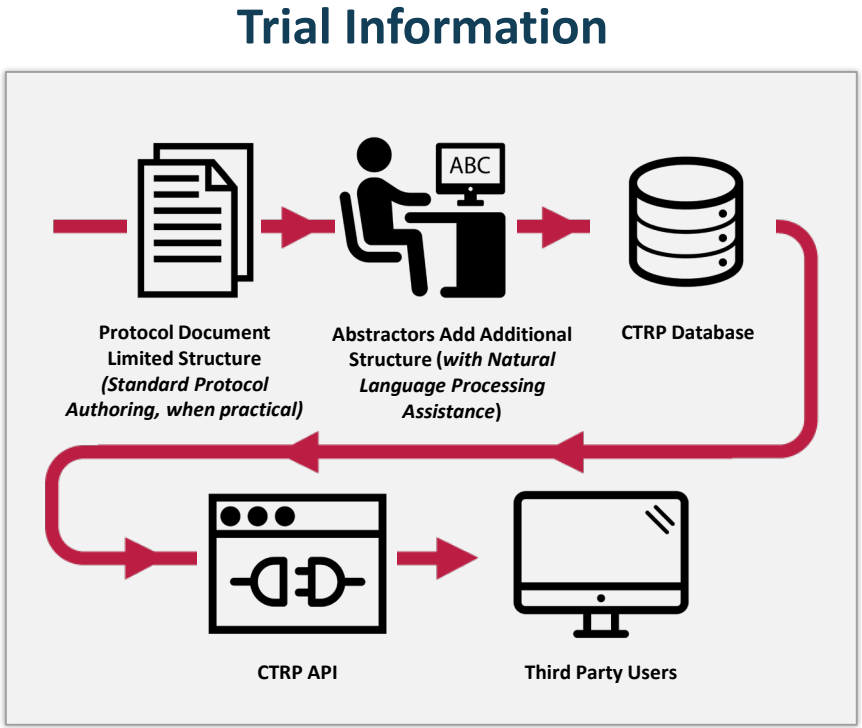
Gathering Information and Engaging Stakeholders

- CTAC Clinical Trials Informatics Working Group
- Teleconferences and Meetings
- Request for Information (RFI)
- Collaborating with Data Scientists through the Presidential Innovation Fellows

Clinical Trials Informatics Working Group — 2017

- Identified structuring eligibility criteria as a priority for improving clinical trials search
- Many have attempted to structure eligibility criteria with limited success in some disease or health-care settings
- No efforts to date have systematically structured eligibility criteria in a standardized fashion for use by the broad cancer clinical trial community

What is Structuring?



Structuring: Express information in the protocol document, such as eligibility criteria, in a consistent format

Approaches to Structuring:

- Standardize eligibility criteria at the point of protocol authoring
- Apply standard ontology or terminology to eligibility criteria
  - Human abstractors
  - Application of Natural Language Processing and Artificial Intelligence to improve efficiency

Standardizing, Structuring and Coding
Example: HIV Eligibility Criteria in Three Trials

Trial	Free Text in Protocol	Standardized Text	Structured and Coded
1	Patients with clinically significant illnesses which could compromise participation in the study, including, but not limited to, active or uncontrolled infection, immune deficiencies, known human immunodeficiency virus (HIV) infection requiring antiretroviral therapy are not eligible	HIV positive with antiretroviral therapy excluded	(C15175 = NO) OR (C15175=YES) OR (C15175 = YES AND C94631 = NO)
2	Known human immunodeficiency virus (HIV)-positive patients on combination antiretroviral therapy are ineligible	HIV positive with antiretroviral therapy excluded	(C15175 = NO) OR (C15175=YES) OR (C15175 = YES AND C94631 = NO)
3	Patients must not have any known immune deficiencies; patients with immune deficiency are at increased risk of lethal infections when treated with marrow-suppressive therapy; therefore, known human immunodeficiency virus (HIV) positive patients receiving combination anti-retroviral therapy are excluded from the study	HIV positive with antiretroviral therapy excluded	(C15175 = NO) OR (C15175=YES) OR (C15175 = YES AND C94631 = NO)

Common Themes from Stakeholder Engagements

- Structured eligibility criteria improves search
- Efforts to improve search or match patients to trials are limited by:
  - Lack of standards
  - Extensive human curation involved
  - Natural Language Processing (NLP) will help, but still requires additional human curation
- NCI should take the lead in structuring eligibility criteria
  - Viewed as an honest broker for identifying approach, terminology and standards
- Many express enthusiasm and excitement to collaborate with NCI on this complex problem

Strategies for Matching Patients to Clinical Trials

- Questions that impact searching:
  - What and how to structure eligibility criteria
  - Methods and models to search or match patients to trials
  - Technologies that might assist with structuring/searching/matching
  - Approaches to collaboration and moving forward
  - Incentivizing structuring of eligibility criteria and matching systems
  - Additional factors that should be considered

RFI: NOT-CA-063
Response period:
April 11th - June 15th

RFI Respondents

CATEGORY	NO. OF RESPONSES
Advocacy Organizations	3
Patients	6
Professional Societies	2
Academic Organizations	13
Private Sector Companies	15
TOTAL	**39**

RFI Responses: Overarching Considerations

- It is difficult to structure eligibility criteria
- Set realistic timeframes
- Involve experts in change management and human centered design
- Structuring is fundamental to enable technology-fueled solutions

RFI Respondents: Common Themes

- Standard and structured eligibility criteria should be developed
- Automated processes can be used to support data curation
  - Some manual effort will likely be required
- Interoperability and data standards are key to facilitate matching patients to information in EHR (desirable outcome)

RFI Respondents: Common Themes (continued)

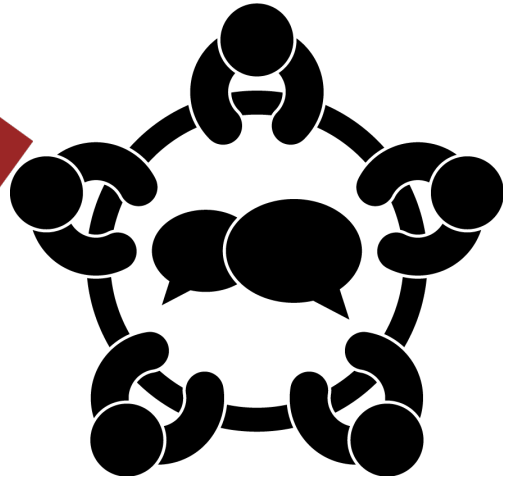
- Create or adopt data standards for eligibility criteria
- Integrate presentation of clinical trials into the clinic workflow
- Suggestions for improving clinical trial search:
  - Search interfaces should be user specific
  - Present eligibility criteria (and other clinical trial information) in patient friendly language

Collaborating with Data Scientists

TOP Health

NIH Data Science
Collaborative Hackathon

Stakeholders



Roundtables

Summary

- Making cancer clinical trials easier to find is a complex problem
- Solution will require engagement of stakeholders across the cancer clinical trials ecosystem
- The Clinical Trial Informatics Working Group (CTIWG) recommended that NCI structure eligibility criteria to improve clinical trial searching.
- NCI's Clinical Trials Reporting Program Database could contribute to the solution by adding additional structure to trial registration records
- Structuring trial information is only part of the solution

Next Steps

- Communicating findings of Landscape Analysis to NCI Advisory Boards
  - National Council of Research Advocate (NCRA)
  - Clinical Trials and Translational Research Advisory Committee (CTAC)
- Exploring standardizing protocol authoring for NCI network trials (e.g. NCI Experimental Therapeutics Clinical Trials Network)
- Working with the stakeholders across the ecosystem to develop an action plan

Question for CTAC

- Are there other strategies or additional factors to take into consideration?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