# Knowledge, Impact and Ethical Issues of Cancer Genomics among Oncologists

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## Abstract

Rapid advances in cancer genomic technologies not only affected testing and treatment but also have resulted in innumerable possibilities for research. This study was conducted to assess current knowledge of clinical cancer genomics, research, related ethical issues, and future impact among oncologists to help direct tailored competency-based curriculum development. A web-based survey was developed and organized into four sections: demographic information, cancer genomics knowledge, oncologists' perception of cancer genomics' future impact; and related ethical issues. Ninety percent of respondents were Egyptians, 83% knew what cancer genomics is and 66% knew its basic areas. Eighty-three % thought that cancer genomics will have an impact in the next 5 years. Nearly half (46%) of the respondents thought that there is a clear boundary between cancer genomics research and clinical care. Most oncologists refused using genetic data sharing (80%) or data transfer (79%) to third parties without consent. The core competencies of the proposed curriculum were then developed. There were 20 core competencies organized in two main domains: knowledge and skills (12 on knowledge and 8 on skills) for cancer genomics and associated ethics. Our findings could benchmark standards for postgraduate curriculum development of cancer genomics and its related ethics issues.


## Introduction

**Cancer Genomics and Impact:**

Genomic testing is increasingly recommended to inform clinical diagnosis and treatment decision-making in oncology particularly in breast and/or ovarian cancer.[1–5] Genomic testing includes germline testing for inherited cancers, somatic tumor testing and/or paired tumor and germline samples. Testing modalities vary from single gene testing, multi-gene panel tests, whole exome, and genome sequencing, to novel genomic biomarkers such as tumor mutational burden. Interpreting of genomic alterations identified from sequencing is key in determining eligibility for targeted therapies. Rapid advances in cancer genomic technologies not only affected testing and treatment but also have resulted in innumerable possibilities for research. CRISPR/Cas9 which is a gene editing technology has emerged and advanced rapidly as a stable, efficient, simple technology that may lead to further breakthroughs in the field of precision oncology. [6]

**Ethical issues of cancer genomics raised in clinical practice:**

Integrating genomics into clinical oncology raises several ethical issues include inequitable access to services, voluntary versus mandatory testing and screening, full disclosure of information ensured by an informed consent, confidentiality versus duties to relatives at genetic risk, privacy of genetic information, return of results issues and ethical issues related to gene therapy and consequently gene editing.[7–9]

**Ethical issues of cancer genomics raised in Research:**

While clinical practice seeks to improve health outcomes for cancer patients, research pursues generalizable knowledge. The difference between clinical practice and research leads to differences in legal obligations, ethical duties, and governing regulations covering clinicians and researchers, as well as separate sets of rights and protections owed to patients and research subjects.[10]

The increasingly blurred boundary between cancer genomics research and clinical practice, which have historically been kept clear. Recently they have sometimes been integrated raising questions about what ethical principles should govern this practice; those of clinical care or those of research?[11]

**Oncologists' education:**

As involved oncologists face complex decisions regarding genomic testing, interpretation of results, treatment decisions based on the clinical actionability of genomic results,[12] genomics research and gene therapy, so involved oncologists should have sufficient knowledge and skills in cancer genomics.[13]

Many options have become available to fill gaps in physician knowledge e.g., organizations have been formed to support genomic education for physicians, websites have been developed to provide webinars on various genomics topics and resources for educating physicians,[14,15] data repositories, interprofessional education, and even emails are being used to disseminate genomic information to physicians.[16,17]

Competency-based curriculum development in medical education was first introduced by WHO, influenced by the need for medical education to better meet public health needs in both developed and developing nations.[18] Recently, van Melle et al defined and delineated the core components of CBME.[19]

The National Comprehensive National Network (NCCN) clinical practice guidelines in oncology issued breast, ovarian and/or pancreatic cancer genetic assessment and genetic/familial high-risk assessment: colorectal as well as including the genetic testing and impact on treatment decision for different other cancers in other clinical practice guidelines. The NCCN elaborated indications of genetic testing, interpretation of genetic results and subsequent management decisions.[20,21]

This study was conducted to assess the current knowledge of clinical cancer genomics, cancer genomics research, their related ethical considerations among oncologists and their perception of cancer genomics impact for the next five years, to help direct tailored pedagogy and training for curriculum development to meet the growing demand for precision oncology, genomics testing and targeted therapy in clinical practice and research.

## Material And Methods

We developed a survey for postgraduate candidates to cope with the rapid expansion of cancer genomics for effective cancer care and cancer research. The survey assesses current knowledge of cancer genomics and associated ethics issues. This survey would identify the gap of knowledge in cancer genomics and associated ethics issues to identify the needed core competencies in cancer genomics and associated ethics issues for oncologists. A literature review was performed to retrieve English articles published from 2014 to 2019. The words: “genetics”, “genomics”, “cancer genetics”, “cancer genomics”, “genetic testing”, “new genomic technologies”, “whole genome sequencing”, “genome editing” and “CRISPR-Cas9” were searched for to formulate the knowledge questions. The words: “genetics ethics”, “genomics ethics”, “cancer genetics ethics”, “cancer genomics ethics”, “ethics of cancer genomics research and clinical care”, “international genomic research collaboration”, “privacy, and data security in the cloud computing environment of genomic data”, and “informed consent in genomics” were searched for to formulate the ethics questions. To identify the core competencies for developing the competency-based curriculum was developed through performing a robust literature review. The words “competency-based medical education”, “genetic and genomic learning needs of oncologists”, “clinical skills education”, “methodology of curriculum development” were searched for.

The survey was organized into four sections: the first section included demographic information of oncologists: such as gender, years of practicing oncology and the number of cancer patients they treated the last year. The second section included questions about knowledge of cancer genomics topics. The third section included questions about the oncologists' perception about cancer genomics' future impact in the next 5 years. The last section included questions about various ethical issues related to cancer genomics. The included ethical issues were questions about the boundary between cancer genomics research and clinical care, international genomic research collaboration, privacy, and data security in the cloud computing environment, and the informed consent.

Question types were chosen to be easy to understand, requires little efforts from respondents and give easy-to-analyze answers. Abou two thirds (65%) of the questions were closed ended questions that can be answered with one word, “yes” or “no” or “do not know”. To know in which aspect the impact of cancer genomics in the next 5 years, respondents were given multiple-choice questions (MCQ) with different options to choose from. Rating questions with a scale of answer options were chosen for respondents to represent their opinion about their current knowledge state.

After developing the survey, the survey was evaluated an expert in clinical oncology and is a reviewer of genomic research to build content and scientific validity of the survey. The minimum age was changed from 18 to 22 years as the targeted oncologists are all postgraduates. Also, the expert suggested that respondents are preferred to be Egyptians although input of other nationalities would be highly valuable as this curriculum is mainly intended to postgraduate Egyptian oncologists.

Then the survey was validated by oncologists of various academic background to be representative of the future respondents of the survey for content and face validity. There were residents, assistant lecturers, lecturers, assistant professors, and professors. Oncologists answered the survey questions to provide their feedback on aspects they found difficult to answer and/or could be improved. There were two questions that needed modifications to improve participant understanding of questions (table 1).

**Table (1) The Pilot survey feedback and amendments**:

| Question | Summarized Feedback | Outcome: question changed into: |
|---|---|---|
| Place of work:<br>- University<br>- Research Center<br>- Hospital<br>- Other | Some oncologists work in a hospital affiliated to a university. | Place of work:<br>- Hospital affiliated to a university<br>- Research Center<br>- Hospital<br>- Other |
| Can Commercial involvement be included in cancer genomic research, kindly express your point of view. | The wording of commercial involvement is unclear. | Commercial involvement (selling or buying) can be included in cancer genomic research without patient consent:<br>- Yes<br>- No<br>- Do not know |

The feedback was incorporated in the survey, the final survey consisted of 29 questions.

**Data collection**

Oncologists aged 22 years or more of both sexes were invited to participate in this survey, participation was voluntary, informed consent was taken from research participants, and the survey was anonymous. The study started after Research Ethics committee approval, the survey link (https://forms.office.com/Pages/DesignPage.aspx?lang=en-US&origin=OfficeDotCom&route=Start#FormId=qoXLTRRxHUmdHrlgE0RO8sJIrFXmDk5HgJLR5gOeVa5UQUs4Q01MRDlJUEcyWk4xWUxMMFZYNEszTy4u) was forwarded via Oncologist mails, telephone numbers, known WhatsApp Oncology groups.

## Results

As of March 20th, 2021, 70 oncologists responded to the survey. Average time for completion of the survey was 8.09minutes as shown in Microsoft forms. The demographics questions and the impact of cancer genomics questions were answered by all oncologists. For questions assessing current knowledge of cancer genomics, 4 questions were answered by 70 and 4 questions were answered by 69 oncologists. For the associated ethics considerations, 10 questions were answered by 70 and 2 were answered by 69 oncologists. The last question was an open question for oncologists to add comments if they wish. The respondents were 40 females and 30 males. Most were Egyptians (91%), 1 Arab, 1 African and 1 Asian. Ninety percent of respondents treated or assisted in treatment of more than 100 patients in the previous year. Seventy percent worked in a hospital affiliated to a university. About half (56%) worked as oncologists for more than 10 years, 23% for 5–10 years and 21% less than 5 years.

**Current knowledge of cancer genomics**

Most oncologists (83%) knew what cancer genomics is, 66% knew its basic areas. To assess the level of knowledge, a rating score was used in the survey. A score of 1 = “little knowledge”, 2= “knowledgeable”, 3= “very knowledgeable”, and 4= “expert”. And each oncologist was asked which score describes him well. Twenty-eight oncologists (40%) described themselves as having only little knowledge in basic genetic principles, the same number (40%) described themselves as knowledgeable, 12 oncologists (17.4%) described themselves as very knowledgeable and one (1.4%) described himself or herself as an expert (Fig. 1).

Using the same score to assess current knowledge level of new genomic technologies, nearly half (45%) described themselves as having only little knowledge, (39%) described themselves as knowledgeable, 15% described themselves as very knowledgeable and 1% described himself or herself as an expert (Fig. 2).

About two thirds of respondents knew whole genome sequencing (WGS) process (66%) and its aim (72%), genome editing (73%). For a question “A recent approach to genome editing is known as CRISPR-Cas9, which is short for clustered regularly interspaced short palindromic repeats and CRISPR-associated protein 9” and to choose an answer of yes, or no, or do not know. About a quarter of the respondents (27%) knew that CRISPR-Cas9 is a genomic editing approach.

**Perception of the impact of cancer genomics in the next 5 years (Future role)**

Eleven oncologists did not answer this question. Of the 59 who answered this question, (83%) agreed that cancer genomics will have an impact in the next 5 years.

There were 257 responses to the following question because the answer for this multiple-choice question could be more than one answer. Cancer genomics impact was believed to be mainly in selecting a course of treatment and on survival (Fig. (3).

**Current knowledge of ethical issues related to cancer genomics**

Nearly half of the respondents thought that there is a clear boundary between cancer genomics research and clinical care (46%). For international genomic research collaboration, the respondents were divided between setting conditions for international genetic collaboration to be ethical, or unconditioned collaboration or do not know if unconditioned collaboration is ethical or not (36%, 33% and 31% respectively). Nearly half of respondents did not know that current privacy and security of genomic data in the cloud computing environment are enough or not. For the informed consent, most oncologists approved that the consent should be written in details (88%), refused to use stored samples further genomic research without patient's consent (77%), refused data sharing usage without patient consent (80%), refused data transfer to third parties without patient consent (79%), refused commercial involvement (selling or buying) can be included in cancer genomic research without patient consent (74%). About half of oncologists thought that e-consent using patient portals as social media is not enough for cancer genomics (59%), refused genomic and health-related data linkage without patient consent (49%), refused genomic research data and health-related data linkage without patient consent (49%).

After data collection, analysis of the survey results was done. One of the authors (I.S.) was the Head of scientific committee of the affiliated oncology department. She was responsible for conversion the oncology curriculum in her department into a credit hours curriculum that conforms with CBME and her faculty bylaws. The core competencies of the proposed curriculum of cancer genomics and associated ethics issues for postgraduate oncologists were developed. The competencies were organized in two main domains: knowledge and skills.

***Cancer Genomics Core Competencies:***

Knowledge:

- Understand Genomics, its basic areas of genomics.
- Understand the basic genetic principles (inherited patterns).
- Understand indications of genomic testing (especially the whole genome sequencing), benefits, and limitations in routine clinical care and research
- Understand Genome editing (also called gene editing) technology including CRISPR-Cas9, its benefits, risks, and limitations in routine clinical care and research
- Know examples of cancer genomics use in testing, genetic counselling, and therapy in routine clinical care and research.

Skills:

- Ability to apply the most recent international guidelines in genetic testing in routine clinical care and research.
- Ability to use genetic test results, interpretation, and their clinical implications.
- Ability to apply the most recent international guidelines to manage patients with genetic conditions
- Ability to communicate to patients their genetic condition, and its implications

***Ethics of cancer genomics:***

Knowledge:

- Understand the boundary between cancer genomics research and clinical care.
- Understand the ethics of International genomic research collaboration.
- Understand the limitations of privacy and security of genomic data in the cloud computing environment.
- Understand ethical issues associated with informed consent and use of stored samples, e-consent, genomic data sharing, data transfer to third parties, linking genomic research data and health-related data, commercial involvement (selling or buying) in genomic research.
- Recognize cultural, and ethical perspectives when utilizing genetic information and services.
- Appreciate the sensitivity of genetic information.
- Recognize when personal values regarding social and cultural issues may impact or interfere with care provided to patients.

Skills:

- Ability to differentiate between cancer genomics research and routine clinical care.
- Ability to apply ethics in genetic testing, international genomic research collaboration, using stored samples, data sharing, data transfer to third parties, linking genomic research data and health-related data and commercial involvement (selling or buying).
- Ability to safeguard privacy and confidentiality of genetic information of patients while disclosing genetic results.
- Demonstrate tailoring information and services to patient's culture, knowledge, and language level.

## Discussion

Not only genetic testing is increasingly recommended for patients after being diagnosed with cancer, but the possibility of inherited cancer predisposition may be raised which has profound potential implications for the patient and other family members.[22]

Chow-White conducted a survey of 31 medical oncologists (MO) from British Columbia, Canada, who were actively involved in a clinical genomics trial called Personalized Onco-Genomics (POG) to measure MOs' level of genomic knowledge in cancer medicine. The findings showed a low to moderate level of genomic literacy among MOs. MOs located outside the Vancouver area (the major urban center) reported less knowledge about new genetics technologies compared to those located in the major metropolitan area (26.7 vs 73.3%, $P < 0.07$, Fisher exact test). Forty-two percent of all MOs thought medical training programs do not offer enough genomic training. The data suggested a high need for educational interventions to increase genomic literacy among MOs.[23]

Recently clinical practice guidelines were issued for cancer genetic assessment and genetic/familial high-risk assessment, but these guidelines did not include associated ethics considerations or ethics associated with international genomic collaboration for countries that do not have genetic testing facilities. Moreover, the Clinical Medical Research Regulation Law (the Egyptian law for the conduct of research) which was issued on December 23$^{d}$, 2020 which is aligned with international guidelines for health research ethics review, regulates various ethical issues related to genomics research as refusing broad consenting for genomic research and adopting a specific consent for each research. The abovementioned reasons triggered a need for an adapted cancer genomics and its associated ethics curriculum. To develop the curriculum, identification of the educational gap was needed. To identify the educational need, a literature review for developing a survey and its related questions was done. We created a survey to assess the current knowledge of clinical cancer genomics, cancer genomics research, their related ethical considerations among oncologists and their perception of cancer genomics impact for the next five years, to help direct tailored pedagogy and training for curriculum development to meet the growing demand for precision oncology, genomics testing and targeted therapy in clinical practice and research.

To bridge the educational gap in clinical practice and research, the needed core competencies of a proposed curriculum were developed. As this curriculum will constitute a small but important section in oncologists' curricula, it could not and cannot include all topics related to cancer genomics and associated ethical issues. So, prioritization of topics according to issues encountered in our clinical practice and research and literature was done. Formal training followed by assessment was chosen for cancer genomics and associated ethical issues to be our method of education for several reasons: being a rather new discipline with scarce medical background in the formal undergraduate medical education. Also, a lack of confidence among oncologists about their knowledge of genomics, and ability to make treatment recommendations based on genomic data, has been reported.[24,25] Furthermore, a third of oncologists did not feel confident communicating personalized genomic results to their patients,[26] oncologists were most confident in using somatic single-gene tests, followed by multi-marker tumor panel tests and are least confident when using whole genome or exome sequencing to guide patient care.[27]

During the validation of the survey, oncologists were chosen to represent various stakeholders i.e., residents, assistant lecturers, lecturers, associate professors, and professors. This is consistent with the recommendation that all relevant stakeholders should include their input during CBME framework development in health professions.[28]

Advances in oncology translational research, is gradually ushering genomic discoveries and technologies into the cancer practice. The rapid pace of these advances is opening a gap between the knowledge available about the clinical relevance of genomic information and the ability of oncologists to include such information in their medical practices. This educational gap threatens to be rate limiting to the clinical adoption of cancer genomics.

In their study, Tognetto et al., 2019 proposed 15 core competencies (10 of which on knowledge, 2 on skills and 3 on attitudes) in a curriculum for non-physician health professionals not working in genetic services.[29] On reviewing these competencies, they were felt to be unsuitable for our oncologists' curriculum, as they do not address the daily needs for cancer care or cancer research in our country. Moreover, they did not address ethical issues that may be raised during genetic testing interpretation of genetic results, resultant decisions for patients' treatment or issues related to cancer genomics research.

So, in this study we developed a survey to assess the educational gap in both the cancer genomic in clinical care and research and their associated ethics issues to help oncologists make a more effective and ethical set of decisions for their cancer patients. International core competencies developed so far has not included associated ethics issues in cancer genomics practice or research. In our proposed curriculum, we propose 20 core competencies (12 on knowledge and 8 on skills), 5 on knowledge and 4 on skills for cancer genomics and 7 on knowledge and 4 on skills for cancer genomics ethics. Our findings could benchmark standards for postgraduate curriculum development of cancer genomics and its related ethics issues.

## Limitations

Attitudes were not incorporated in the survey to complete the CBME curriculum, instead we chose to include ethics competencies. The ethics core competencies deal with more important and relevant issues related to our community needs.

## Conclusion

The accelerating pace of cancer genomics in clinical practice and research together with development of related ethical issues resulted in necessity of assessment of educational needs to integrate cancer genomics into our postgraduate education system. A tailored CBME curriculum was proposed based on survey results. The proposed core competencies provide direction for curriculum content, help meet increasing education demands and consequent improvement in oncology care and research.

## Abbreviations

Clustered Regularly Interspaced Short Palindromic Repeats CRISPR

CRISPR associated protein 9 CRISPR/Cas9

World Health Organization WHO

Competency-Based Medical Education CBME

The National Comprehensive National Network NCCN

Multiple Choice Questions MCQ

Whole Genome Sequence WGS

## Declarations


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### Conflict of Interest

The authors declare no conflict of interest.


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The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript.


### Author Contribution Statement

All authors have substantial contributions to the conception of the work, the acquisition, analysis, interpretation of data for the work. They drafted the work, and finally approved the version to be published, and agreed to be accountable for all aspects of the work.

### Informed Consent

An Informed Consent was taken from all research participants.

### Data Availability Statement

The datasets generated during the current study are available in the [figshare] repository and can be accessed at https://figshare.com.

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## Figures

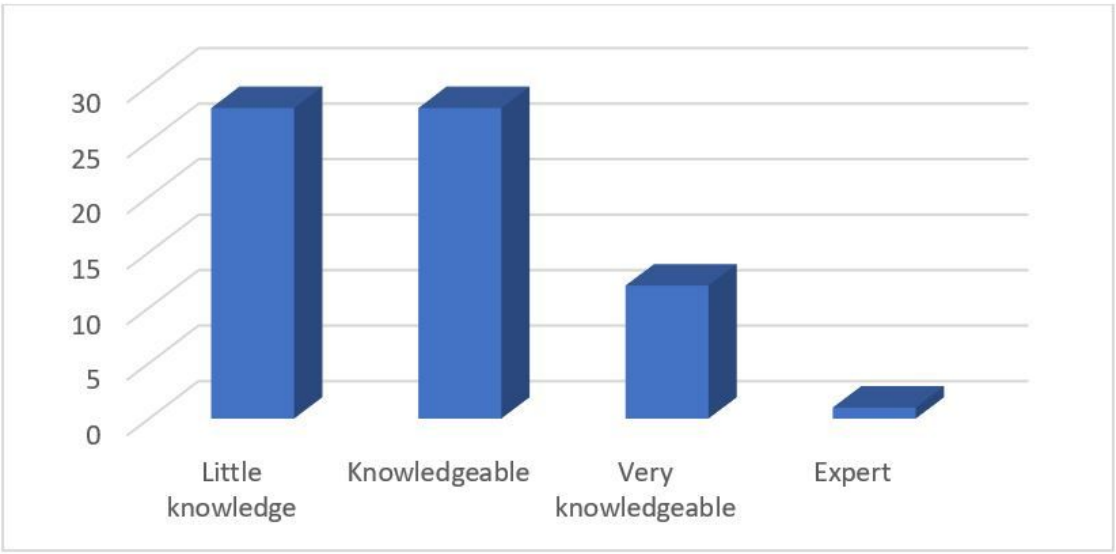


**Figure 1**

Current level of knowledge in basic genetic principles

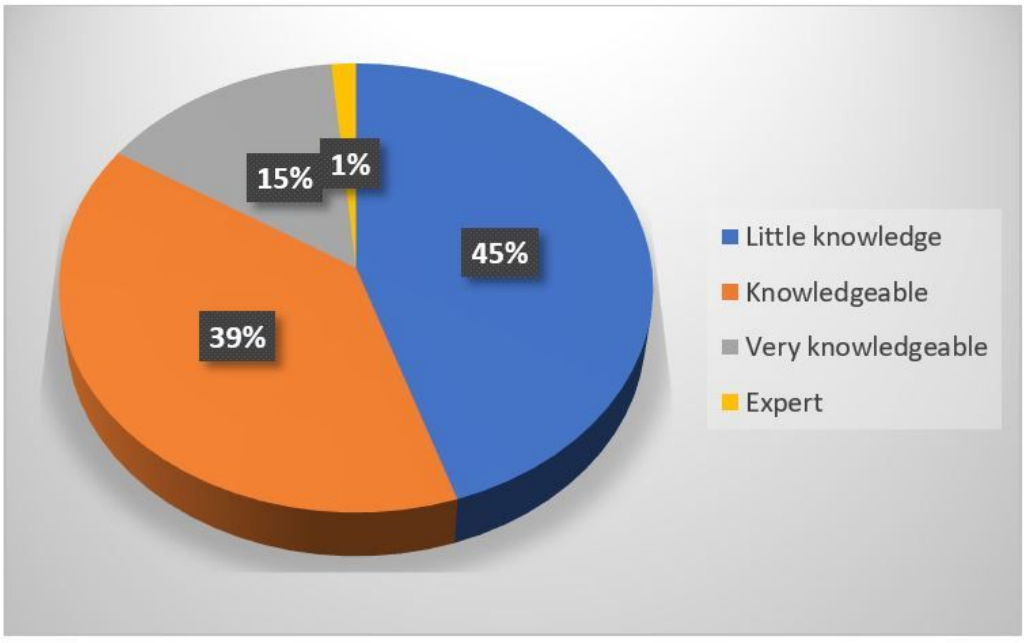


**Figure 2**

Current knowledge level of new genomic technologies

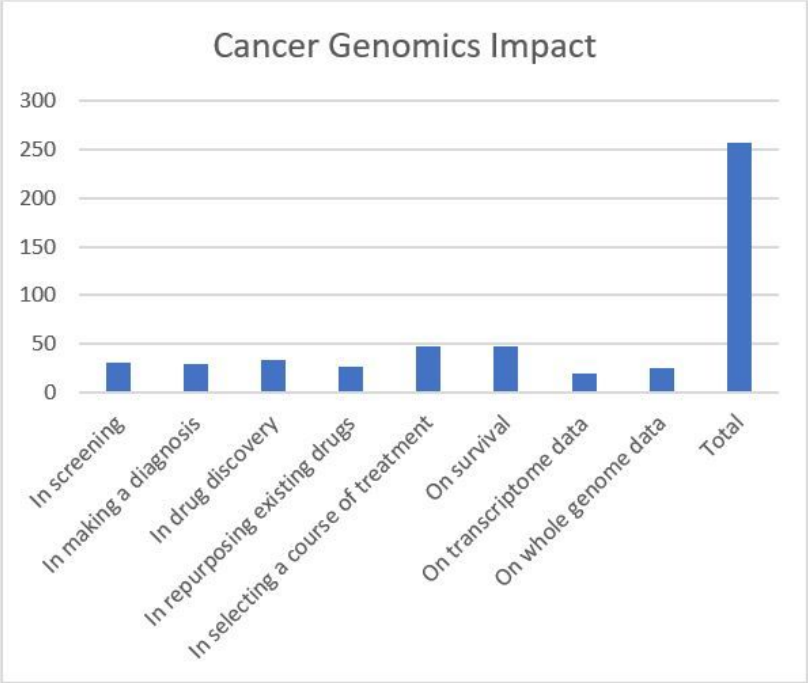


**Figure 3**

Cancer genomics impact areas