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**MICHIGAN CANCER CONSORTIUM**



*Report on a Pilot Study of  
Cancer Clinical Trial Enrollment  
in Michigan 2000*

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Nancy McCrohan, PhD  
Darcy Wilson, MPH  
Michigan Public Health Institute

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***Public and Private Partners Working Together to Reduce Cancer Mortality***

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Questions and comments may be directed to Nancy McCrohan at [nmccroha@mphi.org](mailto:nmccroha@mphi.org).

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## ***EXECUTIVE SUMMARY***

The purpose of the study was originally intended to be a baseline study but evolved into a pilot test of feasible methods and materials in preparation for a baseline study on the enrollment of patients into cancer clinical trials in Michigan. Obtaining a baseline fulfills one of the goals of the Michigan Cancer Consortium Initiative (MCCI) priority objective related to cancer clinical trials. The goal of the clinical cancer research priority objective is to double the number and increase the diversity of participants enrolled in clinical trials by 2005.

This pilot study was needed for the following reasons.

- The baseline data is critical to assessing the attainment of other goals related to enrollment in cancer clinical trials.
- Currently there is no single source of information on persons enrolled in cancer clinical trials in the state.
- Clinical trials play a major role in the development of safe and effective treatments to reduce the societal burden of disease.

The targeted population was institutions throughout Michigan that engaged in quality trials that advanced the science. The sampling plan did not target all sites that recruited patients into trials, but rather, focused on institutions that held responsibility for aggregating trial accrual numbers, typically those reporting these numbers to the funder. The targeted population included the following.

- Universities.
- Hospitals.
- Cancer centers.
- Community Clinical Oncology Programs (CCOPs).

The findings of this pilot study on enrollment in cancer clinical trials for the year 2000 in Michigan include the following.

- There were a total of approximately 3,711 patients enrolled in cancer clinical trials for the year 2000 in Michigan.
- There were more females than males enrolled in cancer clinical trials.
- More than half of enrollees were participating in National Institutes of Health (NIH) trials.
- Although the study was a census, it is known that industry and prevention trial enrollment numbers were underreported.
- About 7 in 10 persons enrolled in cancer clinical trials were participating in treatment trials.
- More than 8 in 10 enrollees (83.1%) in trials were white, 14.6% Black, 1% Asian, and other race/ethnicities each represented less than one percent of patients enrolled in cancer clinical trials in Michigan.

The proportion of cancer patients statewide that were enrolled in cancer clinical trials (treatment and cancer control trials only) was calculated for this report. This proportion was based on

incidence counts of cancer patients statewide (diagnosed 1997 to 1999 and alive January 1, 1999), and represents a pool of those potentially eligible for clinical trials. Estimates of the proportion of cancer patients who were enrolled in cancer clinical trials revealed that proportionally Blacks (3.0%) and other minorities (7.3%) were more likely to be enrolled in clinical trials compared to whites (2.4%).

The pilot study led to the following conclusions.

- This work represents an effort to develop a sample frame and viable methodology for collecting cancer clinical trial enrollment numbers in Michigan.
- The data provided an estimate of the number of patients (and their demographic characteristics) that were enrolled into cancer clinical trials in 2000 in Michigan.
- The pilot study has informed the development of future data collection that can provide an approximate baseline from which to measure progress in the Michigan Cancer Consortium clinical trial priority objective of increasing numbers and diversity of persons enrolled in trials.
- A high degree of accuracy within the data remains elusive, due to the nature of collecting unmonitored data from a wide variety of sources.
- Improvements for future data collection methods are outlined in the report.
- It is desirable that this study continues until 2005.

In future reports, changes over time in enrollment numbers will need to be assessed in context, considering a variety of factors, such as changes in the following areas.

- Efforts to increase trial participation.
- Availability of enrollment data.
- Responsiveness to data collection efforts.
- Scientific advances in the cancer arena.

## ***OVERVIEW***

### ***Purpose***

The Michigan Cancer Consortium (MCC) is sponsoring a statewide collaborative effort in support of cancer prevention and control activities. To date, the MCC's Initiative (MCCI) has led to the development of ten prioritized cancer control objectives, a strategic plan for their implementation, and early implementation steps. The goal of the clinical cancer research priority objective is to double the number and increase the diversity of participants enrolled in clinical trials by 2005. The Michigan Society of Hematology and Oncology has taken the lead on activities related to this objective. One of these activities is to establish a baseline for current participation in cancer clinical trials in Michigan. Currently there is no single source of information on persons enrolled in cancer clinical trials in the state. Clinical trials play a major role in the development of safe and effective treatments to reduce the societal burden of disease.

The purpose of the current study was originally intended to be a baseline study but evolved into a pilot test of feasible methods and materials in preparation for a baseline study on the enrollment of patients into cancer clinical trials in Michigan. Obtaining a baseline fulfills one of the goals of the Initiative's priority objective related to cancer clinical trials. The data is critical to assessing the attainment of other goals related to enrollment in cancer clinical trials. The current study established a design for future data collection efforts.

To begin the pilot study of patients enrolled in cancer clinical trials in Michigan, three preliminary goals were identified. The first goal was to determine a sampling method and frame. The second goal was to determine what data elements would be of use. And finally, the third goal was to pilot test the instrument and protocols.

## ***METHODOLOGY***

### ***Sampling Frame and Response Rates***

It was determined that there were no existing databases summarizing cancer clinical trials that would be sufficiently broad to capture the data of interest. It was also determined that surveying providers would not be fruitful or feasible. Therefore, a sampling of institutions was needed.

More specifically, the targeted population that could provide the data of interest was institutions throughout Michigan that engaged in quality trials that advanced the science. These included Universities, Hospitals, Cancer Centers, and Community Clinical Oncology Programs (CCOPs). The sampling plan did not necessarily target all sites that recruited patients into trials, but rather, institutions that held responsibility for aggregating trial enrollment numbers, typically those responsible for reporting these numbers to the funder. These institutions were conceptualized as "responsible parties."

The sample frame was developed through several routes. The first source for the sampling frame was developed by Michigan Society of Hematology and Oncology (MSHO), consisted of a list of major cancer centers and universities involved in cancer research in 2000, and was dubbed the "primary list" of institutions eligible for inclusion in the sampling frame (see Table A).

***Table A: Primary List of Eligible Institutions***

- Ann Arbor Regional Community Clinical Oncology Program
- Grand Rapids Community Clinical Oncology Program
- Henry Ford Hospital System
- Karmanos Cancer Institute
- Michigan State University – NSABP Office
- University of Michigan Cancer Center
- West Michigan Cancer Center

The second source for the sampling frame came from hospitals. To determine eligibility for the cancer clinical trials pilot study, screening letters were sent to all acute care hospitals and FSO-ASCs (freestanding surgical outpatient facility – ambulatory surgical center) in the state of Michigan (“hospitals,” n=195). All hospitals were surveyed using a screening tool that queried whether the hospitals conducted cancer clinical trials during 2000 (see Appendix B). Specifically, hospitals were asked if they had an Oncology department, whether they conducted cancer clinical trials in 2000, and if they had an office that coordinated cancer clinical trials.

Responses to the screening instrument dictated whether hospitals were eligible to be in the final sampling frame. Hospitals were deemed eligible if they indicated that they had conducted cancer clinical trials in 2000. This screening tool also elicited contact information for the clinical trials data manager or other individual responsible for data management at the institution.

A third source for the sampling frame came from snowball contacts. Respondents were asked to indicate if they knew of other investigators that may have accrued patients into trials that may not have been reported to the primary list institutions or the eligible hospitals. Snowball letters were also sent to universities that had human medicine programs, targeting departments such as Nursing, Human Medicine, and Family Practice. Virtually all the potential respondents identified in the snowball phase were affiliated with universities.

Other sources for the sampling frame were investigated and considered, including targeting cooperative groups, and finding investigators not associated with major cancer centers on the primary list. From the CancerNet website, the names of investigators who were accruing patients into trials in Michigan were gleaned. The search pattern used for this was: open active trials; any treatment modality; all phases; and any type of trial. At the time of searching (July 2001) there were about 300 trials fitting this description. Upon closer scrutiny, however, it was determined that virtually all these investigators had enrollment sites in Michigan within the primary list of institutions, from which data was being collected.

Consideration was given as to whether the sample frame ought to include corporations that sponsor industry trials. However such corporations were not found to be viable sources for data.

Data from these sources would; overlap with enrollment sites, not have Michigan-only data (separate from other enrollment sites) available, and need to consist of a virtual census of industry trials in order to be useful.

In its final form, the sample frame consisted of (1) major cancer centers, (2) hospitals, (3) and universities, including snowball investigators.

Both the eligible hospitals and the snowball investigators were sent data collection forms that first queried whether they had trials that were associated with any institution on the primary list. They were instructed to provide enrollment numbers only for studies in which the enrollment numbers were not reported to one of the institutions on the primary list. This protocol was put in place in an effort to minimize overlapping in the reporting of enrollment numbers.

In addition, follow-up phone calls were made to the contact persons in the primary list of institutions. During these phone calls questions were asked regarding affiliations. This was an effort to clarify affiliations in order to reduce overlap, and assess the need for further follow-up with hospital non-responders. If an institution on the primary list reported receiving data from a non-responder, it was assumed data (that would ordinarily be reported to the primary institution) from the non-responder was already accounted for. In these instances, non-responders were no longer pursued for further follow-up. It is possible that non-responders had intramural or industry trials data (that would not ordinarily be reported to a primary institution) that was then not captured in the pilot study.

For the hospital screening, an initial mailing resulted in a 53% response rate within 4 weeks. A second mailing brought the response rate up to 80%. Of the 156 surveys returned, 36 (23.1%) were deemed eligible for the pilot study. About three-fourths (76.4%) indicated they had an Oncology department and more than half (54.9%) indicated that they had an office that coordinated cancer clinical trials. Upon additional research and discussion, 15 additional sites were identified as eligible through the CancerNet website and other resources, for a total of 51 eligible institutions.

The eligible institutions were mailed a data request packet that included a cover letter, instructions, and data collection forms. (See Appendix C) Of the 53 eligible institutions, 33 responded to the first mailing, and 7 responded to follow up mailings, resulting in a 75.5% response rate for the eligible institutions. All primary list institutions participated in the study; however, the University of Michigan prevention numbers were unavailable.

### ***Data Elements***

The second goal was to determine what data elements were desirable. Based on the Priority Goal, an understanding of the total number and the diversity of participants enrolled in clinical cancer research trials was the focus. The exact parameters of the demographic data elements were based on an examination of cancer research publications, web databases, and recommendations from the MCC Clinical Trials working group.

The parameters that defined the data of interest were open active trials only, Michigan residents at Michigan sites only, any hematology and oncology trials, any type or stage of cancer, and year 2000 only (See Table B).

The key data elements sought were aggregate numbers of patients enrolled in cancer clinical trials and demographic information on enrollees. The demographic variables of interest were ‘Gender’, ‘Age’, and ‘Race/Ethnicity’. These key data elements were broken down by sponsor type (NIH; Intramural; Industry), type of trial (Prevention; Control; Treatment), and phase of trial (Phase I; II; III; Unknown). (See Table C for definitions).

***Table B: Parameters, Demographic Variables, and Data Elements in the Pilot Study***

<p><b>Parameters</b></p> <ul style="list-style-type: none"> <li>• Open active trials only</li> <li>• Michigan residents at Michigan sites only</li> <li>• Hematology and oncology trials only</li> <li>• Any type or stage of cancer</li> <li>• Year 2000 only</li> </ul>
<p><b>Demographic Variables</b></p> <ul style="list-style-type: none"> <li>• Gender</li> <li>• Age</li> <li>• Race/Ethnicity</li> </ul>
<p><b>Data Elements</b></p> <ul style="list-style-type: none"> <li>• Sponsor type <ul style="list-style-type: none"> <li>▪ NIH</li> <li>▪ Intramural</li> <li>▪ Industry</li> </ul> </li> <li>• Type of trial <ul style="list-style-type: none"> <li>▪ Prevention</li> <li>▪ Control</li> <li>▪ Treatment</li> </ul> </li> <li>• Phase of trial <ul style="list-style-type: none"> <li>▪ Phase I</li> <li>▪ Phase II</li> <li>▪ Phase III</li> <li>▪ Phase unknown/not applicable</li> </ul> </li> </ul>

**Table C: Definition of Data Elements in the Pilot Study**

<b>Data Elements</b>	<b>Element Definition</b>
<b>Sponsor type</b>	
▪ NIH	Primarily funded or sponsored by any NIH office, including NCI
▪ Intramural	Primarily funded or sponsored by your institution
▪ Industry	Primarily funded or sponsored by a for-profit corporation
<b>Type of trial</b>	
▪ Prevention	Study ways of reducing the risk of getting cancer in one of two ways; 1) by doing something, such as exercising or quitting smoking (Action studies), or 2) by taking something, such as certain medicines, vitamins or minerals (Agent studies)
▪ Control	Basic and applied research in the behavioral, social, and population sciences to create or enhance interventions that, independently or in combination with biomedical approaches, reduce cancer risk, incidence, morbidity, and mortality
▪ Treatment	Test new treatments (like a new cancer drug, new approaches to surgery or radiation therapy, new combinations of treatments, or new methods such as gene therapy)
<b>Phase of trial</b>	
▪ Phase I	Evaluate how a new drug should be given, how often, and what dose is safe in humans
▪ Phase II	Continues to test the safety of the drug, and begins to evaluate how well the new drug works on a particular type of cancer
▪ Phase III	Test a new drug, a combination of drugs, or a new surgical procedure in comparison to the current standard for treatment
▪ Unknown/not applicable	Phase is not known or not applicable to study

***Pre-Test***

The third goal was to determine whether desirable data elements would be available from institutions. A pre-test was conducted with four institutions that varied in type and size. The response indicated that the ability of the institution to provide the data requested varied widely. The largest institution was able to provide the data in the desired format. A smaller institution indicated that all the data was on patient charts rather than centrally located. Another institution had a central database containing patient information for clinical trials, but did not necessarily store that data in the same discrete units that were sought, and could not necessarily manipulate the data to provide what was requested.

Based on the pre-test it was thought that institutions on the primary list would be able to provide data within all variables, and that other eligible institutions would have some difficulty, but would fill in where information was accessible. Upon completion of the data collection process, however, it was found that the majority of the primary institutions, as well as other institutions, had difficulty completing one or more variables.

### ***Assessment of the Study Methodology***

The sampling methodology chosen had some strengths and weaknesses. The mode of data collection, using hardcopy and postal mailings, seemed satisfactory. Offering the option to fax or postal mail completed data collection forms also worked well.

The strength of the sample frame was that it was developed based on input from experts who could identify major participants in cancer clinical trials, as well as from screening information from the hospitals. The adequacy of the sample frame in future data collection will depend on the ability to stay updated on the evolution of institutions, their cancer clinical trial status, and mergers. Continuous development of the sample frame will also require updates on appropriate contact persons within institutions.

One of the strengths of the study methods was an emphasis on reaching the appropriate contact persons within the eligible institutions. Project staff spent a considerable amount of time and effort engaged in this activity. Most of the institutional contacts began with high-level directors and administrators, with a request that project staff be directed to clinical trial data managers. Multiple efforts at follow-up, usually via email and telephone calls, were required for many institutions. This identification of appropriate contact persons was a critical component of data collection, and took substantially longer than anticipated.

The enrollment data collected has several limitations that potentially impact its validity. One source of potential error in the data is inaccuracy in reporting by an institution. No verification or auditing of any institution's data sources took place. The size of potential error from this source cannot be estimated.

Another source of potential error in the data is overlapping in reporting from enrollment sites and from responsible institutions. Overlapping is possible but hopefully minimized by the instructions that accompanied the data collection forms. The instructions were also specifically referred to in cover letters. In addition, as previously mentioned, follow-up phone calls were made to the primary institutions in an effort to identify affiliations, and hence prevent overlapping.

Another source of potential error in the data collection is omission of enrollment numbers. As indicated previously, there were non-responders to the hospital data collection. Omission due to non-responders who actually had data that could have been reported is possible. However, based on expert input, these specific non-responding institutions' enrollment numbers would be expected to be none or few. In an effort to gather comprehensive data different departments within universities were sent data collection forms. Half of these departments responded, and of these, 75% indicated that they reported all of their data to the major cancer center within their university, while the remainder submitted enrollment data for the pilot study. However, it is

possible there are other departments or other investigators (that would not be reporting to the major cancer center within their university) that had conducted trials, but were not contacted. In addition to any non-responders, it is known that there is partial data missing from one of the primary institutions, which likely represents a large number of prevention trial enrollment cases not captured in the pilot study.

Another aspect of the methodology that needs addressing is whether the data collection instrument was adequate. The actual completion of the data collection instrument did not appear to cause respondents any difficulty. However, the ease of extracting the data elements requested in the instrument varied between institutions. There was variability in level of specificity that institutions were able to provide. Nearly every institution had trouble providing one or more data elements, or providing the level of detail requested. The degree of difficulty in extracting data was related to how and where it was stored, the discrete units in which data was stored, and the availability and capacity of staff to extract data. Data was stored in electronic databases, spreadsheets, logsheets, and hardcopy patient files. Some institutions went to a great deal of effort, consulting multiple data sources, to provide enrollment numbers. Some institutions could not provide certain types of data because they were stored separately from other types of data and/or were not stored in any aggregate form (usually industry trials). More than one institution shared with the researchers that they hoped to improve, expand, or create the management or software for enrollment data. At least one institution shared with researchers that their system worked for the purpose of reporting to the primary funder, but had limited capacity to manipulate the data for other reporting purposes.

The only data element that nearly all institutions had trouble reporting was phase (if broken out by other data elements). Many institutions also had trouble reporting age. Therefore, future instruments have been revised so that both phase and age will be requested in a more aggregate form (See Appendix D). This instrument may be further revised based on input from a focus group of clinical trial data managers during the fall of 2002.

### ***Validity of the Pilot 2000 Data***

Because of the difficulty in quantifying potential errors, whether from omission, overlapping, or inaccuracy, an effort was taken to find alternate sources of enrollment estimates with which to compare pilot 2000 data. The only viable data source for validation was the cancer clinical trial data from NCI's (National Cancer Institute) CDUS (Clinical Data Update System) data set.

The CDUS data was requested and received. However, the pilot 2000 data could not be adequately verified using CDUS data because of differences between the two data sets. The differences were in the (1) scope or universe of trials included (known in advance of request), and (2) comparability in data elements (unanticipated at the time of request).

First, the CDUS database does not include all NCI sponsored trials. The database includes only those trials that utilize a Cancer Therapy Evaluation Program (CTEP) supplied investigational agent or all trials that involve the NCI Cooperative Groups and consortiums (regardless of whether they include the CTEP agent or not). Although the CDUS database can be defined by what it includes, it is difficult to quantify how many trials or what percent of trials are not reported by CDUS. In contrast, the pilot 2000 data collection requested enrollment numbers for

all NCI/NIH sponsored trials, which should result in higher aggregate numbers than those reported by CDUS.

Secondly, although the request for CDUS data included a breakdown by trial type (prevention, treatment, cancer control), the CDUS protocol does not include this element in their database. Nonetheless, the data managers at Capital Technology Information Services, Inc (CTIS, the organization responsible for managing the CDUS data set) made inquiries that allowed them to categorize most of the studies in the CDUS data set as 'Treatment', 'Prevention', or 'Cancer Control'. However, some studies were returned labeled 'Undetermined'. In addition, there were many data element breakdowns in the pilot data that were reported as unknown. This made comparison to the CDUS data (with much fewer unknowns) difficult.

An overall comparison between the pilot 2000 and CDUS data sets show that the pilot data included 462 more enrollment cases than the CDUS data. This may reflect overlapping in reporting the pilot study (i.e., error), or the inclusion of studies in the pilot that are (appropriately) not included in the CDUS data. There were discrepancies in enrollment numbers in element breakdowns as well. These differences are difficult to interpret due to the reasons discussed previously.

CDUS data has been conducted in a consistent format since 1997. Because enrollment reporting is a funder requirement, it would seem that that CDUS can provide a relatively complete and comprehensive data set for the studies that it tracks. This is evidenced by the small amount of “unknown” or missing data in the CDUS data set. This data may therefore be more accurate than the pilot 2000 efforts, for the studies that it tracks.

### ***Recommendations for Future Methodology***

It is recommended that changes in future data collection methods include the addition of NCI data from the CDUS data source, for reporting of all NIH/NCI data. This would entirely replace the gathering of NCI data directly from the institutions. Trials that are not reported by CDUS would be not be sought by other means. (See *Validity of the Pilot 2000 Data* discussion). This change would necessitate attention to, and consideration of, any changes in the types of NCI studies reported so that comparability from year to year can be assessed.

Intramural and industry data, however, would continue as before to be requested directly from the primary institutions and hospitals. This decrease in the amount and type of requested data is likely to lessen the burden of reporting for most responding institutions which also can increase response rates and may improve validity of data.

In order to effectively survey institutions regarding their intramural and industry enrollment numbers, it is recommended that persons knowledgeable about their institution's internal relationships and clinical trials data management operations be consulted prior to data collection regarding the methodology.

Affiliations and management changes within institutions needs to be monitored. The adequacy of the sample frame in future data collection will depend on the ability to stay updated on the

evolution of institutions, their cancer clinical trial status, and mergers. Continuous development of the sample frame will also require updates on appropriate contact persons within institutions.

It will not become feasible to monitor, verify, or audit the accuracy of each institution's data reports. This limitation will need to be noted in any report of findings.

Efforts to avoid underreporting must be addressed through a combination of tracking affiliations, increasing response rates, enhancing the sample frame, and personal follow-up with non-responders.

Efforts to avoid overlapping in reporting from enrollment sites and from responsible institutions must be addressed through a combination of tracking affiliations, simplifying data collection, and increasing the likelihood of instructions being used by respondents.

Future methodology decisions must be based on recognition of the wide variability in the data management and data systems employed by various institutions. Data collection improvements must be focused on making reasonable data requests with which the majority of institutions are able to comply. The proposed future instrument has been revised so that both 'Phase' and 'Age' will be requested in a more aggregate form (See Appendix D). This instrument will be further revised based on input from a focus group of clinical trial data managers during the fall of 2002.

In future data collection, attention needs to be directed toward how data elements are captured and managed (See *Data Management and Analyses* discussion). For example, efforts will need to include follow-up of any data reports in which missing or unknown data appears to be implied rather than listed. This will eliminate the amount of deduced missing cases, instead introducing a process that can potentially capture data errors. Efforts need to be undertaken to systematically inquire as to whether certain data elements (eg., industry sponsors) are missing. In future data collection, "not applicable" and "unknown" will be separate categories for 'Phase.'

### ***Data Management and Analyses***

A tracking system was developed in MS Access software to manage the sample frame and data collection implementation information, and a data entry system was developed in MS Excel software to manage the enrollment data. Entry of data collected from institutions into the study data set was verified 100%.

In the data collection form, respondents were provided with cells in which to place missing or unknown data. In some cases respondents did not use these cells, instead leaving blank the number of cases missing a characteristic. Because of this the numbers of missing cases in the tables reflect a combination of 'reported missing' and 'deduced missing' cases. For example, if under NIH prevention trials, a respondent reported 6 males and 8 females, 12 white and 2 Black persons, but only listed the age categories for 13 cases, then 1 case was deduced to be missing 'age.'

Data analysis consisted of a series of summations of enrollment numbers. Because the data is a census rather than a sample from a universe, confidence intervals are not reported. However, it should be indicated that at least one institution stated that they accrued patients into industry

trials but could not provide the data on the enrollees due to the manner in which the data was stored or managed. Therefore, it is known that the industry trial enrollment numbers are underreported.

Because there are many potential sources of error in the data that are difficult to quantify, statistical significance of findings is not reported, which appropriately avoids the appearance of precision in the data.

'Phase' data were collected in a manner such that 'not applicable' and 'unknown' were combined. Because these data were collapsed at the point of data collection, it is not possible in this data analysis to separate out which were 'not applicable' and which were 'unknown.' One institution indicated that all the cases they listed in the "unknown or not applicable" cell were in fact "not applicable." This one institution accounted for approximately 24% of all of the "unknown or not applicable" data. In future data collection, 'not applicable' and 'unknown' will be separate categories for 'phase.'

## ***FINDINGS***

The demographic characteristics of the patients enrolled in cancer clinical trials in Michigan in 2000 are shown on Table 1. The total number of enrollees overall in cancer clinical trials was 3,711. About 13.1% of enrollment data was missing gender information and about 9.4% was missing race/ethnicity data. Where gender information was available, 57.2% of enrollees were women. Where race/ethnicity was available, 83.1% of enrollees were white, 14.6% Black, 1% Asian, and each of the other race/ethnicities represented less than one percent of patients enrolled in cancer clinical trials in Michigan. Further breakdown of the data revealed that three institutions accounted for 82.5% of all Black enrollment into clinical trials in the state for 2000.

About 37.4% of enrollment data was missing age information. In studies where age information was available about 6.1% were juvenile, 7.3% were in their twenties or thirties, nearly half (45.5%) were between the ages of 40 and 59, and about 4 in 10 enrollees were age 60 and older. Due to the high proportion of missing age data, breakdown of data by demographic characteristics discussed later in this report does not include age data.

Pilot Study of Cancer Clinical Trial Enrollment in Michigan 2000

**Table 1: Demographic Characteristics of all Patients Enrolled in Cancer Clinical Trials**

Includes all Sponsors, all Trial Types, all Phases

<b>Demographics</b>	<b>N</b>	<b>%</b>	<b>Valid %*</b>
<b>Gender</b>			
Male	1379	37.2%	42.8%
Female	1846	49.7%	57.2%
Unknown	486	13.1%	
<b>Race/Ethnicity</b>			
White, not Hispanic	2794	75.3%	83.1%
Hispanic	25	0.7%	0.7%
Black, not Hispanic	492	13.3%	14.6%
Native Hawaiian or other Pacific Islander	0	0.0%	0.0%
Asian	32	0.9%	1.0%
American Indian or Alaskan Native	9	0.2%	0.3%
Other	12	0.3%	0.4%
Unknown	347	9.4%	
<b>Age</b>			
0-14	121	3.3%	5.2%
15-19	22	0.6%	0.9%
20-29	44	1.2%	1.9%
30-39	125	3.4%	5.4%
40-49	431	11.6%	18.6%
50-59	626	16.9%	26.9%
60-69	569	15.3%	24.5%
70-79	344	9.3%	14.8%
80+	41	1.1%	1.8%
Unknown	1388	37.4%	
<b>Total</b>	<b>3711</b>		
* Valid % reflects all non-missing data (i.e., excludes missing and not applicable).			

An understanding of the number of cancer patients statewide, i.e., a pool of those potentially eligible for clinical trials, was needed to put the study findings into perspective. Statewide cancer figures were developed using basic case counts from the Michigan Cancer Surveillance Program (statewide registry) by staff in the Division for Vital Records and Health Statistics, Michigan Department of Community Health. These figures consisted of the number of people alive in 1999 who had been diagnosed with cancer from 1997 to 1999 and were alive on January 1, 1999. Survival status was determined by using information on vital status obtained through death links to Michigan deaths through 2001 and National Death Index links through 1997. Essentially all cases were counted if a death had not been identified as having occurred before 1/1/1999 (See Table 2). In other words, these figures provide a three-year time frame to represent the pool of cancer patients potentially eligible for enrollment into a clinical trial.

Using the incidence of cancer patients in a given time frame to represent those potentially eligible for clinical trials is an approximation of actual eligibility. This question is complicated based on the window when individuals may be likely to enter clinical trials, and the related question of eligibility for a cancer clinical trial. These issues need to be considered as the study continues. The window of opportunity when a person could enter a clinical cancer trial varies by type of trial. The window of entry into a treatment trial generally would be within 1-2 years of diagnosis (some people would start after an standard treatment, some would start immediately after diagnosis). Treatment trials can include surgery, chemotherapy, and radiation therapies, so the point of entry into a trial after a diagnosis can be complicated. Another issue to consider is when a cancer reoccurrence happens and how this would be reported. In addition, there are specific criteria for entry into the various clinical trials, and depending on whether they are early detection, treatment, or cancer support trials, which impacts the definition of eligibility.

Table 2 summarizes the number and characteristics of patients enrolled in treatment and cancer control trials in 2000, the number of patients statewide who were potentially eligible for clinical trials in 1999 (i.e., estimated prevalence of eligible patients), and the estimated proportion of cancer patients enrolled in treatment or cancer control trials in Michigan in 2000. Prevention trials are not represented in this table. The proportion of cancer patients enrolled into clinical trials was based on estimated statewide number of eligible patients and the number of individuals enrolled in (treatment and cancer control) clinical trials per the pilot study.

As shown on Table 2, the resulting estimates suggest that overall approximately 2.6% of cancer patients were enrolled in treatment or cancer control clinical trials in the year 2000. Blacks, at 3.0%, and other minorities (7.3%) were more likely than Whites (2.4%) to be enrolled in cancer clinical trials. Because of the high proportion of missing data in the study for both gender and age, breakdowns by gender and age are not provided in Table 2.

Pilot Study of Cancer Clinical Trial Enrollment in Michigan 2000

**Table 2: Number and Percent of Patients Enrolled in Treatment & Control Cancer Clinical Trials**

Does not include Prevention enrollment. Includes all Sponsors, all Phases

	<b>Number of Patients Enrolled in Cancer Clinical Trials, Estimated Statewide 2000</b>	<b>Cancer Patients Statewide Potentially Eligible for Clinical Trial Enrollment in 1999*</b>	<b>Percent of Patients Enrolled in Cancer Clinical Trials, Estimated Statewide 2000</b>
<b>Race and Total</b>	N	N	%
<b>Race/Ethnicity (Crude estimated alive)</b>			
White, not Hispanic	2570	109267	2.4%
Black	463	15447	3.0%
Other	74	1012	7.3%
Unknown	345	5477	
<b>Total</b>	3452	131203	2.6%
Patients diagnosed in 1997 and 1998 and alive on January 1, 1999, and patients diagnosed in 1999. Data provided by Division for Vital Records and Health Statistics, Michigan Department of Community Health.			

Table 3 reports on the number of cancer clinical trial enrollees by sponsorship, trial type and phase of trial. Of all enrollees, more than half (55.3%) were enrolled in NIH trials, more than one-quarter (25.8%) in intramural trials, and 18.9% were in industry trials. However, it is known that industry trials are underreported as discussed earlier.

Of all enrollees, about 7 in 10 (69.2%) were enrolled in treatment trials, nearly one-quarter (23.8%) in cancer control trials, and 7% were enrolled in prevention trials. Although the study was a census, it is known that prevention trial enrollment numbers were underreported.

More than one-third (37.5%) of trial phase data were either not reported or not applicable. As discussed in the methodology section, missing and not applicable phase data were combined at the point of data collection. Where phase data was available and applicable, the majority of patients (56.6%) were enrolled in phase three trials and nearly 4 in 10 (39.0%) were in phase two trials.

Pilot Study of Cancer Clinical Trial Enrollment in Michigan 2000

**Table 3: Enrollment by Sponsor Type, Trial Type, and Phase**

<b>Trial Characteristics</b>	<b>N</b>	<b>%</b>	<b>Valid %**</b>
<b>Sponsor</b>			
NIH	2052	55.3%	55.3%
Intramural	957	25.8%	25.8%
Industry*	702	18.9%	18.9%
<b>Trial Type</b>			
Prevention*	259	7.0%	7.0%
Treatment	2567	69.2%	69.2%
Cancer Control	885	23.8%	23.8%
<b>Phase</b>			
One	104	2.8%	4.5%
Two	904	24.4%	39.0%
Three	1312	35.4%	56.6%
Unknown or NA	1391	37.5%	
* Industry trial and prevention trial enrollment numbers are known to be underreported.			
**Valid % reflects all non-missing data (i.e., excludes missing and not applicable).			

Tables 4, 5 and 6 highlight sponsorship (NIH, intramural, industry) information. Table 4 shows trial sponsorship by trial type (prevention, intramural, industry). Regardless of sponsorship, the majority of patients were enrolled in treatment trials. Patients enrolled in industry trials, however, were more likely to be in treatment trials (84.2%) compared to patients in intramural or NIH trials (76.1% and 60.8% respectively). Patients enrolled in NIH trials were more likely to be in prevention trials (9.0%) compared to patients in intramural or industry trials (3.7% and

5.7% respectively). Patients enrolled in NIH trials were also more likely to be in cancer control trials (30.2%) compared to patients in intramural or industry trials (20.3% and 10.1% respectively).

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Pilot Study on Cancer Clinical Trial Enrollment in Michigan 2000

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**Table 4: Sponsor by Trial Type**

All Phases

Trial Types	NIH		Intramural		Industry*		Trial Type Totals	
	N	%	N	%	N	%	N	%
<b>Prevention*</b>	184	9.0%	35	3.7%	40	5.7%	259	7.0%
<b>Treatment</b>	1248	60.8%	728	76.1%	591	84.2%	2567	69.2%
<b>Cancer Control</b>	620	30.2%	194	20.3%	71	10.1%	885	23.8%

\* Industry trial and prevention trial enrollment numbers are known to be underreported.

Table 5 illustrates trial sponsorship by phase of trial. As previously mentioned, more than one-third of data regarding patient enrollment had phase data either missing or not applicable. This was most notable in intramural trial data, where about half (49.1%) of phase data was either missing or not applicable.

Where phase data was available and applicable, enrollment data indicate that patients in NIH trials were more likely to be in phase three trials (80.3%), whereas patients enrolled in intramural and industry trials were more likely to be enrolled in phase two trials (85.2% and 61.4% respectively).

Table 6 demonstrates trial sponsorship by demographic characteristics of enrollees. More than one-fifth of NIH enrollee data (21.6%) is missing gender data. Considering only valid percents (where gender data was available), the majority of enrollees in trials were females, regardless of sponsorship type. Specifically, females made up 60.1% of patients in NIH trials, 53.9% of patients in intramural trials, and 55.1% of patients in industry trials.

As noted earlier, nearly 9.4% of reported enrollee data overall did not include race/ethnicity data. However, NIH data was missing the most race/ethnicity data (13.4%) and intramural was missing the least (2.6%). Where race data was available, patients in intramural trials were more likely to be Black (18.1%) compared to NIH (12.9%) or industry enrollees (14.2%).

Pilot Study of Cancer Clinical Trial Enrollment in Michigan 2000

**Table 5: Sponsor by Phase**

All Trial Types

Phase	NIH			Intramural			Industry*			Phase Totals		
	N	%	Valid %**	N	%	Valid %**	N	%	Valid %**	N	Total %	Valid %**
<b>One</b>	54	2.6%	3.9%	34	3.6%	7.0%	16	2.3%	3.7%	104	2.8%	4.5%
<b>Two</b>	222	10.8%	15.9%	415	43.4%	85.2%	267	38.0%	61.4%	904	24.4%	39.0%
<b>Three</b>	1122	54.7%	80.3%	38	4.0%	7.8%	152	21.7%	34.9%	1312	35.4%	56.6%
<b>Unknown or NA</b>	654	31.9%		470	49.1%		267	38.0%		1391	37.5%	

\* Industry trial enrollment numbers are known to be underreported.

\*\* Valid % reflects all non-missing data (i.e., excludes missing and not applicable).

Pilot Study of Cancer Clinical Trial Enrollment in Michigan 2000

**Table 6: Sponsor Type by Demographic**

Includes all Trial Types, all Phases

Demographics	NIH			Intramural			Industry*			Total Demographic		
	N	%	Valid %**	N	%	Valid %**	N	%	Valid %**	N	%	Valid %**
<b>Gender</b>												
Male	641	31.2%	39.9%	441	46.1%	46.1%	297	42.3%	44.9%	1379	37.2%	42.8%
Female	967	47.1%	60.1%	515	53.8%	53.9%	364	51.9%	55.1%	1846	49.7%	57.2%
Unknown	444	21.6%		1	0.1%		41	5.8%		486	13.1%	
<b>Race/Ethnicity</b>												
White, not Hispanic	1513	73.7%	85.1%	740	77.3%	79.4%	541	77.1%	82.7%	2794	75.3%	83.1%
Hispanic	16	0.8%	0.9%	7	0.7%	0.8%	2	0.3%	0.3%	25	0.7%	0.7%
Black, not Hispanic	230	11.2%	12.9%	169	17.7%	18.1%	93	13.2%	14.2%	492	13.3%	14.6%
Native Hawaiian or other Pacific Islander	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%	0.0%
Asian	9	0.4%	0.5%	7	0.7%	0.8%	16	2.3%	2.4%	32	0.9%	1.0%
American Indian or Alaskan Native	7	0.3%	0.4%	2	0.2%	0.2%	0	0.0%	0.0%	9	0.2%	0.3%
Other	3	0.1%	0.2%	7	0.7%	0.8%	2	0.3%	0.3%	12	0.3%	0.4%
Unknown	274	13.4%		25	2.6%		48	6.8%		347	9.4%	
* Industry trial enrollment numbers are known to be underreported.												
** Valid % reflects all non-missing data (i.e., excludes missing and not applicable).												

Trial type (prevention, treatment, cancer control) information is highlighted in Tables 7 and 8. In Table 7, trial type is shown broken out by phase. The proportion of trials in which phase data was unknown or not applicable varied widely between trial types. For prevention trials, only 12.4% of phase data was unknown or not applicable. In treatment trials, 32.6% of phase data was unknown or not applicable, and this proportion increased to 59.1% for cancer control trials.

Where phase data was available and applicable, enrollment in phase three trials varied from about half (treatment trials), to two-thirds (cancer control), to about three-quarters (prevention trials) of clinical trial enrollees.

In Table 8, trial type is shown broken out by demographic characteristics of enrollees. The proportion of trials in which gender data was unavailable varied widely between trial types. For prevention trials, only 3.5% of gender data was unknown; in treatment trials 11.8% of gender data was unknown; and in cancer control trials 19.5% of gender data was unknown.

Where gender data was available, the proportion of patients that were female varied widely across trial type. About half of enrollees were female in treatment trials (49.9%), but this increased to 70.2% in cancer control trials and 86.8% in prevention trials.

In terms of race/ethnicity, prevention trial data had the least amount of missing race data (less than 1%). Where race/ethnicity data was available, enrollment in cancer control trials included a higher proportion of Blacks (21.4%) compared to prevention and treatment trials (11.3% and 12.7% respectively).

Pilot Study of Cancer Clinical Trial Enrollment in Michigan 2000

**Table 7: Trial Type by Phase**

All Sponsor types

Phase	Prevention*			Treatment			Cancer Control			Phase Totals		
	N	%	Valid %**	N	%	Valid %**	N	%	Valid %**	N	%	Valid %**
<b>One</b>	0	0.0%	0.0%	104	4.1%	6.0%	0	0.0%	0.0%	104	2.8%	4.5%
<b>Two</b>	53	20.5%	23.3%	731	28.5%	42.2%	120	13.6%	33.1%	904	24.4%	39.0%
<b>Three</b>	174	67.2%	76.7%	896	34.9%	51.8%	242	27.3%	66.9%	1312	35.4%	56.6%
<b>Unknown or NA</b>	32	12.4%		836	32.6%		523	59.1%		1391	37.5%	

\* Prevention trial enrollment numbers are known to be underreported.

\*\* Valid % reflects all non-missing data (i.e., excludes missing and not applicable).

Pilot Study of Cancer Clinical Trial Enrollment in Michigan 2000

**Table 8: Trial Type by Demographic Characteristics**

Includes all Sponsor Types, all Phases

Demographics	Prevention*			Treatment			Cancer Control			Total Demographic		
	N	%	Valid %**	N	%	Valid %**	N	%	Valid %**	N	%	Valid %**
<b>Gender</b>												
Male	33	12.7%	13.2%	1134	44.2%	50.1%	212	24.0%	29.8%	1379	37.2%	42.8%
Female	217	83.8%	86.8%	1129	44.0%	49.9%	500	56.5%	70.2%	1846	49.7%	57.2%
Unknown	9	3.5%		304	11.8%		173	19.5%		486	13.1%	
<b>Race/Ethnicity</b>												
White, not Hispanic	224	86.5%	87.2%	1974	76.9%	85.3%	596	67.3%	75.1%	2794	75.3%	83.1%
Hispanic	0	0.0%	0.0%	17	0.7%	0.7%	8	0.9%	1.0%	25	0.7%	0.7%
Black, not Hispanic	29	11.2%	11.3%	293	11.4%	12.7%	170	19.2%	21.4%	492	13.3%	14.6%
Native Hawaiian or other Pacific Islander	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%	0.0%
Asian	3	1.2%	1.2%	14	0.5%	0.6%	15	1.7%	1.9%	32	0.9%	1.0%
American Indian or Alaskan Native	0	0.0%	0.0%	6	0.2%	0.3%	3	0.3%	0.4%	9	0.2%	0.3%
Other	1	0.4%	0.4%	9	0.4%	0.4%	2	0.2%	0.3%	12	0.3%	0.4%
Unknown	2	0.8%		254	9.9%		91	10.3%		347	9.4%	
* Prevention trial enrollment numbers are known to be underreported.												
** Valid % reflects all non-missing data (i.e., excludes missing and not applicable).												

## ***DISCUSSION***

### ***Discussion of Pilot Study Findings***

This study provided an estimate of the number of patients (and their demographic characteristics) that were enrolled in cancer clinical trials in 2000 in Michigan. The findings of this study indicate that there were 3,711 enrollees in cancer clinical trials for the year 2000 in Michigan. More than half of enrollees were participating in NIH trials. Although the study was a census, it is known that industry and prevention trial enrollment numbers were underreported. About 7 in 10 persons enrolled in cancer clinical trials were participating in treatment trials.

There were more females than males enrolled in trials overall. Females were more likely to be enrolled in NIH studies than in intramural or industry trials. Females were more likely to be enrolled in prevention (86.8%) and cancer control (70.2%) studies than in treatment trials. Males and females were represented in equal proportions in treatment trial enrollment numbers.

More than 8 in 10 enrollees (83.1%) in trials were white, 14.6% Black, 1% Asian, and other race/ethnicities each represented less than one percent of patients enrolled in cancer clinical trials in Michigan. Blacks were more likely to be enrolled in cancer control (21.4%) studies than in prevention and treatment trials. Blacks were also more likely to be enrolled in intramural (18.1%) studies than in industry or NIH trials.

### ***Discussion of Statewide Estimates***

Estimates of the proportion of cancer patients statewide who were enrolled in cancer clinical trials were calculated for this report. Estimates of the pool of patients potentially eligible for clinical trials is complicated based on the window of opportunity when individuals may be likely to enter clinical trials, and the related question of eligibility for a cancer clinical trial. These issues need to be considered as the study continues.

The estimates indicated that overall approximately 2.6% of cancer patients were enrolled in treatment or cancer control clinical trials in the year 2000. This finding is in line with expectations based on anecdotal evidence, and low compared to previous national estimates. This finding lends support to the goal of increasing clinical trial enrollment overall.

Of cancer patients estimated to be enrolled in (treatment or cancer control) cancer clinical trials, proportionally Blacks (3.0%) and other minorities (7.3%) were more likely to be enrolled in clinical trials compared to whites (2.4%). This finding was unexpected; it was thought that the proportion of minority patients enrolled in cancer clinical trials would be low compared to the proportion of white patients.

The reasons for the gap between expectation and finding need to be explored. Alternate explanations could include data accuracy issues, imprecise anecdotal evidence, or misperception of minority enrollment. Because the cell sizes for the number of “other minorities” in particular are small, any error in these cells would be more notable in the proportion-enrolled figure. It may be that perceptions of minority enrollment do not take into account differences based on trial types. For example, it is likely that minority enrollment in prevention trials is low, but minority enrollment in cancer control trials is not.

Another possibility is that the absolute number of minority persons enrolled in trials is low but the proportion of minority persons enrolled in trials is not low. Alternately it is possible that the pilot study is missing data on certain trials, which if included, would give a different picture of minority enrollment.

### ***Summary***

This study represents an effort to develop a sample frame and viable methodology for collecting cancer clinical trial enrollment numbers in Michigan. However, a high degree of accuracy within the data remains elusive, due to the nature of collecting unmonitorable data from a wide variety of sources. There are a variety of activities that could lead to future improvements in the ability to gather valid enrollment data.

At a national level, existing databases that catalog cancer clinical trials could be expanded to include patient enrollment numbers, including demographic characteristics of enrollees. These could potentially be used to provide feedback at a statewide level. Alternately, a statewide registry of trials could be developed that incorporated enrollment numbers.

When defining future directions for the enrollment study, there is a need to identify the types of reports that would be useful to various audiences, and the potential future uses of the data. Based on these considerations, the value of establishment and maintenance of a Michigan clinical trials database can be assessed.

At the institutional level, there are several changes that could enhance future statewide collection and reporting of enrollment data. Institutional improvements in the data systems for storage, management, and reporting of clinical trial enrollment data would improve completeness and validity of future enrollment studies.

In terms of study methods, project staff needs to maintain and develop activities that lead to minimizing data errors and improving response rates in future enrollment studies. These activities could include effective identification of correct contact persons, understanding of institutional affiliations, and simplification of data collection requests.

It is desirable that this study continue until 2005. In future reports, changes over time in enrollment numbers will need to be assessed in context, considering a variety of factors such as changes in efforts to increase trial participation, availability of enrollment data, responsiveness to data collection efforts, and scientific advances in the cancer arena.

## **APPENDICES**

**Appendix A:** Institutions that Responded to Pilot Study

**Appendix B:** Screening Survey

**Appendix C:** Data Collection Materials

**Appendix D:** Proposed Instrument for Future Data Collection

## Appendix A: Institutions that Responded to Pilot Study

Responding Institutions
Ann Arbor Clinical Oncology Program
Battle Creek Health System
Borgess Hospital
Bronson Methodist Hospital
Children's Hospital of Michigan
Community Cancer Care Specialists
Community Health Center of Branch County
Covenant Health Care
Emma L. Bixby Medical Center
Foote Health Center
Genesys Regional Medical Center
Grand Rapids Clinical Oncology Program
Grandview Hospital
Hackley Hospital
Henry Ford Health System
Holland Community Hospital
Hurley Medical Center
Huron Valley - Sinai Hospital
Ingham Regional Medical Center/Breslin Cancer Center
Karmanos Cancer Institute
Lakeland Health System
Lapeer Regional Hospital
Marquette General Hospital
McLaren Regional Cancer Center
Mercy Hospital
Metropolitan Hospital
Michigan Institute of Urology
Michigan State University - NSABP
MidMichigan Medical Center
Mount Clemens General Hospital
Munson Medical Center
North Oakland Medical Centers
Northern Michigan Hospital
Oakwood Hospital and Medical Center
Owosso Health Care
Providence Hospital
Sparrow Regional Cancer Center
Spectrum Health
St. John Hospital & Medical Center
St. John Macomb Hospital
St. Joseph Health Systems
St. Joseph Mercy - Oakland
St. Joseph's Mercy Hospital - Macomb
St. Mary's Medical Center
University of Michigan Cancer Center
West Michigan Cancer Center
William Beaumont Hospital - Troy

## Appendix B: Screening Survey 2000

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MICHIGAN CANCER CONSORTIUM  
Clinical Trials Priority  
Statewide Hospital Screening

**Please circle one response for each of the following questions.**

- 1.) Does your hospital have an Oncology Department? YES NO
- 2.) Does your hospital have an office that coordinates cancer clinical trials? YES NO
- 3.) Did your hospital conduct cancer clinical trials in 2000? YES NO
- 4.) Are you interested in receiving information on the findings of the study that will be conducted this summer? YES NO

**If you answered “Yes” to question 1, 2, or 3,** please provide contact information for the person responsible for monitoring these trials within your institution.

**If you answered “Yes” to question 4 only,** please provide contact information for the person to whom we should send results.

Name \_\_\_\_\_

Title \_\_\_\_\_

E-mail \_\_\_\_\_

Institution \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

*Please respond no later than October 1, 2001*

*Please return to Darcy Wilson, Michigan Public Health Institute,  
MCC Clinical Trials, 3055 Plymouth Rd. Suite 304, Ann Arbor, MI 48105  
OR FAX to Darcy Wilson at 734.669.8837*

## Appendix C: Data Collection Materials 2000

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### Instructions for Completing Clinical Trials Enrollment Form (Hospitals)

#### ***STEP 1: Enter your contact information.***

Please fill in this form with the name and contact information for the person who acts as a data manager for clinical trial enrollment data at your institution (or the person who completed the data collection forms). Please correct the address below as needed.

Name \_\_\_\_\_

Title \_\_\_\_\_

E-mail \_\_\_\_\_

Institution \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

Phone \_(\_\_\_\_\_)\_\_\_\_\_

***STEP 2: Determine eligibility by answering the following questions.***

1) Were any Michigan patients accrued or enrolled into any cancer clinical trials research at your institution in 2000? *Please circle your response.*

**Yes** → Go to next question

**No** → If you answered “No,” please return Step 1 and Step 2 information only. No further data is requested. Please return this to Darcy Wilson by March 15, 2002 at 3055 Plymouth Rd, Suite 204, Ann Arbor, MI 48105 or via Fax (734.669.8837). Please accept our sincere thanks for your interest in this project.

2) Were **all** of your accrual numbers for all your clinical trials in 2000 reported to **any** of the following institutions? *Please circle your response.*

- Karmanos Cancer Institute
- Henry Ford Health System
- University of Michigan Cancer Center
- Michigan State University Cancer Center
- Ann Arbor Regional Community Clinical Oncology Program
- West Michigan Cancer Center
- Grand Rapids Community Clinical Oncology Program

**Yes** → If you answered “Yes,” please return Step 1 and Step 2 information only. No further data is requested. Please return this to Darcy Wilson by March 15, 2002 at 3055 Plymouth Rd, Suite 204, Ann Arbor, MI 48105 or via Fax (734.669.8837). Please accept our sincere thanks for your interest in this project.

**No** → Go to Step 3

3) Please list the names of all the Principal Investigators of the studies that you will report on in the enrollment data form.

- a) \_\_\_\_\_
- b) \_\_\_\_\_
- c) \_\_\_\_\_
- d) \_\_\_\_\_
- e) \_\_\_\_\_

Please return information from **Step 1 and Step 2**, along with the completed enrollment data form, to Darcy Wilson by March 15, 2002 at 3055 Plymouth Rd, Suite 204, Ann Arbor, MI 48105 or via Fax (734.669.8837)

### ***STEP 3: Understand Goals and Criteria***

In Step 2, if you answered “No” to question 1, OR if you answered “Yes” to question 2, we do not require any other data. Please return the contact info and eligibility info (above) to Darcy Wilson by March 15, 2002 at 3055 Plymouth Rd, Suite 204, Ann Arbor, MI 48105 or via Fax (734.669.8837). Please accept our sincere thanks for your interest in this project.

Please read on if you answered otherwise.

We would like to collect specific accrual information for the year 2000 for any cancer clinical trials that accrued patients at your site IF that accrual information has NOT already been reported to one of the institutions listed above. We are seeking information from the institutions listed above and are trying to avoid overlapping reporting.

Please fill out the attached data collection forms for any cancer clinical trials in 2000 in which Michigan patients were accrued ONLY IF the accrual information has not been reported to one of the institutions listed above. If the criteria are met, include accruals from your institution site only.

- We are asking for aggregate (group) numbers of patients across all cancer clinical trials occurring in Michigan sites.
- We are asking for data on:
  - Michigan Residents in Michigan sites only
  - Open, active trials in 2000 only
  - Oncology (including malignant hematology) only
  - Any type or stage of cancer
  - Year 2000 only

### ***STEP 4: Fill out data collection forms***

- 1.) If you have any difficulty completing the data collection form, or accessing the data that is being asked for, please contact us immediately so that we can assist you in problem-solving.
- 2.) Please note that there is a single data collection form for **each** sponsor type: NCI/NIH; Institutional/Intramural; Pharmaceutical. Please complete all three pages.
- 3.) Provide aggregate numbers of patients broken down by gender, race/ethnicity, and age categories.
- 4.) Note that each form asks for numbers of patients broken out by type of trial: Prevention, Treatment and Cancer Control.
- 5.) Note that each form asks for numbers of patients broken out by Phase of trial: Phase 1, Phase 2, Phase 3. **Some investigators may not be able to provide the break out information. IF**

**you are not able to provide patient demographics broken out by phase, please provide the demographics under “phase unknown.”**

- 6.) Refer to the definitions provided on the next page for descriptions of sponsorship, trial type, phases, and race/ethnicity.
- 7.) Please fill in the following information on the data collection forms
  - a. Name of your Institution
  - b. Date when form was completed
  - c. Name of person completing form
  - d. For each cell insert the actual number of patients enrolled in trials at your institution that meet the description for that column and row.
- 8.) Please return information from **Step 1 and Step 2**, along with the completed enrollment data form, to Darcy Wilson by March 15, 2002 at 3055 Plymouth Rd, Suite 204, Ann Arbor, MI 48105 or via Fax (734.669.8837)
- 9.) Questions may be directed to Darcy Wilson (Research Assistant) 734.669.8896, [dwilson@mphi.org](mailto:dwilson@mphi.org), or Nancy McCrohan (Project Manager) 734.669.8895 or [nmccroha@mphi.org](mailto:nmccroha@mphi.org).

## Definition of the Elements

Please use the following definitions to categorize the type of cancer clinical trials and the stage in which it is being conducted within your institution.

### Types of Sponsorship

- NCI/NIH Sponsor: Primarily funded or sponsored by any NIH office, including NCI
- Intramural/Institutional Sponsor: Primarily funded or sponsored by your institution
- Pharmaceutical Sponsor: Primarily funded or sponsored by a For-profit corporation

### Types of Clinical Trials:

- Cancer Control: Basic and applied research in the behavioral, social, and population sciences to create or enhance interventions that, independently or in combination with biomedical approaches to reduce cancer risk, incidence, morbidity, and mortality.
- Prevention: Study ways of reducing the risk of getting cancer in one of two ways; 1) by doing something, such as exercising or quitting smoking (Action studies), or 2) by taking something, such as certain medicines, vitamins or minerals (Agent studies).
- Treatment: Test new treatments (like a new cancer drug, new approaches to surgery or radiation therapy, new combinations of treatments, or new methods such as gene therapy).

### Three Types of Trial Phases

- Phase 1: Evaluate how a new drug should be given, how often, and what dose is safe in humans.
- Phase 2: Continues to test the safety of the drug, and begins to evaluate how well the new drug works on a particular type of cancer.
- Phase 3: Test a new drug, a combination of drugs, or a new surgical procedure in comparison to the current standard for treatment.

### Race/Ethnicity

- White, not of Hispanic Origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.
- Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.
- Black, not of Hispanic origin: A person having origins in any of the black racial groups of Africa.
- Native Hawaiian or other Pacific Islander: A person having origins in any of the original peoples of Hawaii or Pacific Islands including Hawaii, the Philippine Islands and Samoa.
- Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent. This area includes for example, China, India, Japan, and Korea.
- Native North American: A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliations or community recognition.

Michigan Cancer Clinical Trials: Patient Enrollment in 2000  
 Sponsor Type: \_\_\_\_\_

Institution \_\_\_\_\_  
 Completed By \_\_\_\_\_

Date

Trial Type	PREVENTION				TREATMENT				CANCER CONTROL			
	Phase 1	Phase 2	Phase 3	Unknown Phase	Phase 1	Phase 2	Phase 3	Unknown Phase	Phase 1	Phase 2	Phase 3	Unknown Phase
<b>Phase &amp; Demographics</b>												
<b>GENDER</b>												
Male												
Female												
Unknown												
<b>RACE/ETHNICITY</b>												
White, not Hispanic												
Hispanic												
Black, not Hispanic												
Native Hawaiian or other Pacific Islander												
Asian												
American Indian or Alaskan Native												
Other												
Unknown												
<b>AGE</b>												
0-14												
15-19												
20-29												
30-39												
40-49												
50-59												
60-69												
70-79												
80+												
Unknown												

## Appendix D: Proposed Instrument for Future Data Collection

Cancer Clinical Trials in Michigan  
 Patient Enrollment in 2001  
 Sponsored by Industry

Organization:  
 Date completed:  
 Completed by:

Trial Type	PREVENTION	TREATMENT	CANCER CONTROL
Demographics & Phase			
<b>GENDER</b>			
Male			
Female			
Unknown			
<b>RACE/ETHNICITY</b>			
White, not Hispanic			
Hispanic			
Black, not Hispanic			
Native Hawaiian or other Pacific Islander			
Asian			
American Indian or Alaskan Native			
Other			
Unknown			
<b>AGE</b>			
0-14			
15-19			
20-29			
30-39			
40-49			
50-59			
60-69			
70-79			
80+			
Unknown			
<b>PHASE</b>			
Phase 1			
Phase 2			
Phase 3			
Not applicable			
Unknown			

Please return to Darcy Wilson, Michigan Public Health Institute,  
 MCC Clinical Trials, 3055 Plymouth Rd. Suite 304, Ann Arbor, MI 48105  
 OR FAX to Darcy Wilson at 734.669.8837