Data Analysis of Patients Treated Off-protocol
Protocol # DR11-0039

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1.0 Objective:

The objective of this study is to analyze patient data and outcomes for patients treated off-protocol with FDA-approved drugs in a manner similar to the patients treated on a specific protocol or otherwise in the Department of Investigational Cancer Therapeutics at M. D. Anderson Cancer Center.

2.0 Rationale:

Some patients treated in the Department of Investigational Therapeutics are unable to enroll on our clinical protocols for a variety of reasons, such as the patient's insurance refusing to pay for treatment on a clinical trial and not meeting eligibility requirements to be treated on-protocol. These patients are sometimes treated with same the FDA-approved drugs off-protocol, but in a manner similar to the patients on-protocol or are treated with other conventional therapies.

Reports suggest that a large majority of oncologists have discussed and prescribed off-protocol therapies with their patients; however, a large number also believe that patients should be discouraged from pursuing off-protocol therapy (1). To date, no studies have investigated whether patients treated off-protocol have different outcomes than those treated on-protocol. In addition, it would be important to be able to capture this data.

3.0 Type of subjects to be studied

The records from patients treated off-protocol with FDA-approved drugs in the Department of Investigational Cancer Therapeutics at MDACC between 01/01/2004 - 12/31/2020 will be reviewed and their contents recorded in a secured database. Study subjects will be identified by the institution's medical record number and their privacy protected according to institutional and HIPAA guidelines.

Disease Category:
All types of advanced cancer.

4.0 Number of Subjects to be Studied

The number of the records to be used is up to 500 approximately.

5.0 Data Confidentiality Procedures

Health information will be protected and we will maintain the confidentiality of the data obtained from the patient's chart.

Collection of Identifiers
We will collect and securely store patients' identifiers (including name, medical record number and demographic specifications). Each patient will be assigned a study number that will be the only identifier to figure in the analytical file and personal data will not be disclosed in any form. The key linking these numbers will be retained in a securely locked file by the investigator.

Data Storage
Protection of electronic and paper records will be guaranteed. All electronic records will be stored on password-protected institution computers behind the institution firewall. Any paper records will be classified and stored in locked files inside a locked office.

Training of personnel
Only MDACC personnel trained in maintaining confidentiality, the PI and Co-PIs and the research staff, will have access to study records.

Data sharing
Study data will not be shared with any individuals or entities.

Final disposition of study records
These data will be used only for this research study. Data files will be destroyed within 10 years after publication of the findings.

6.0 Procedure to Obtain Waiver of Informed Consent

THIS IS NOT A TREATMENT PROTOCOL. No treatment will be prescribed as part of this protocol. The purpose of the protocol is to collect data on therapy that has been given to patients. This is a chart review that involves no diagnostic or therapeutic intervention. Given the nature of our analysis and that no safety issues are involved, we are requesting a consent waiver. For prospective patients, data will already be in the medical record at the time of chart review and the data that is being collected is part of routine clinical care. It will not involve new data collection.

It is not practical to conduct this research without this waiver for the retrospective portion of the study since the status of the patient is unknown, i.e. whether they are alive or deceased and it is difficult to trace the whereabouts of the patients.

7.0 Study Plan

We plan to review the charts of patients receiving therapy with FDA-approved drugs off-protocol in the Department of Investigational Cancer Therapeutics at M.D. Anderson. The aim of the data collection will be determine whether differences

exists in patient variables (i.e. toxicity, response) between patients treated off-protocol and those treated on-protocol.

We will conduct this study using clinical records of patients treated off-protocol in the Department of Investigational Cancer Therapeutics. The demographic data to be collected from patients whose charts will be analyzed will include variables such as age, gender, primary cancer, stage of the disease, performance status, treatment characteristics (i.e., number and type of prior therapies), disease status, adverse events, laboratory data (i.e., complete blood count/differential/platelets, tumor markers), and treatment outcomes.

HIPAA privacy and confidentiality guidelines will be followed. The database will be secured in our Department server. A Data coordinator has been recruited to undertake this project. The information derived from these observations will help the investigators formulate research questions and projects to develop future prospective studies.

The statistical analysis will be performed in a descriptive fashion with paired and multivariable analyses. The analyses will be reported using summary tables, figures, and data listings. Continuous variables will be summarized using the mean, standard deviation, median, minimum, and maximum.

8.0 References

1. Peppercorn J, Burstein H, Miller FG, Winer E, and Joffe S. Self-reported practices and attitudes of US oncologists regarding off-protocol therapy. 2008. J Clin Oncol. Dec 20; 26 (36):5994-6000.