OMB# 0925-0753 (Exp.5/31/2024)

DTL Signed on 13-OCT-2023

Protocol Information

CTEP Document Number	Phase	Lead Protocol Organization
A021502	III	ALLIANCE

Protocol Title

Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair

Site Information

Research Site Name	Site ID	Address
[redacted]	76105	[redacted] Bochum, 44791 DE

Clinical Investigator Information

Person ID	Name of Clinical Investigator
[redacted]	[redacted]

IRB of Record

IRB #	IRB Name	Address
[redacted]	[redacted]	[redacted]

Laboratory Information

No protocol specific labs required.

Delegation of Tasks Log			
#	Ctep Person ID	Person	Research Task
Clinical Investigator			
1	[redacted]	[redacted]	Consenting Person,Eligibility Assessment,End Point Assessment,Enrolling Person/Treating Investigator,HP Assessments,IND Prescribing,Investigational Product Accountability,OPEN Registrar,Tox Assessment
Sub-Investigators			
1	[redacted]	[redacted]	DTL Administrator,OPEN Registrar,Rave CRA
2	[redacted]	[redacted]	Consenting Person,DTL Administrator,Eligibility Assessment,End Point Assessment,Enrolling Person/Treating Investigator,HP Assessments,IND Prescribing,OPEN Registrar,Rave CRA,Tox Assessment
3	[redacted]	[redacted]	OPEN Registrar,Rave CRA
4	[redacted]	[redacted]	Consenting Person,Eligibility Assessment,End Point Assessment,Enrolling Person/Treating Investigator,HP Assessments,IND Prescribing,Tox Assessment
5	[redacted]	[redacted]	Consenting Person,Eligibility Assessment,End Point Assessment,Enrolling Person/Treating Investigator,HP Assessments,IND Prescribing,Tox Assessment
6	[redacted]	[redacted]	OPEN Registrar,Rave CRA
7	[redacted]	[redacted]	Consenting Person
8	[redacted]	[redacted]	Consenting Person,Eligibility Assessment,End Point Assessment,Enrolling Person/Treating Investigator,HP Assessments,IND Prescribing,Tox Assessment

Commitments

I agree to conduct the protocol(s) in accordance with the relevant documents and will only make changes in a protocol after notifying the sponsor or responsible organization, except when necessary to protect the safety, rights, or welfare of subjects.
I agree to personally conduct or supervise the described investigation(s).
I agree to inform any patients, or any persons used as controls, that the agents/interventions are being used for investigational purposes (if applicable) and I will ensure that the requirements relating to obtaining informed consent and Independent Ethics Committee (IEC) review and approval in ICH E6, national and regional legislation, and the Declaration of Helsinki are met.
I agree to report to the sponsor or responsible organization any adverse experiences that occur in the course of the investigation(s) in accordance with ICH E6, national and regional legislation, and the Declaration of Helsinki. I have read and understand the information in the investigator's brochure (if an investigational agent is being used) or approved product labeling/marketing authorization literature, including the potential risks and side effects of the agent.
I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the protocol(s) are informed about their obligations in meeting the above commitments.
I agree to maintain adequate and accurate records and to make those records available for inspection in accordance with ICH E6, national and regional legislation, and the Declaration of Helsinki.
I will ensure that an IEC that complies with the requirements of ICH E6, national and regional legislation, and the Declaration of Helsinki will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IEC all changes on the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IEC approval, except where necessary to eliminate apparent immediate hazards to human subjects.
I agree to comply with all other requirements, regarding obligations of clinical investigators and all other pertinent requirements in ICH E6, national and regional legislation, and the Declaration of Helsinki.

Signature

Signature	Date	Printed Name
[redacted]	13-OCT-2023	[redacted]

I have acknowledged and agree that my electronic signature is the legally binding equivalent to my handwritten signature. Whenever I execute an electronic signature, it has the same validity and meaning as my handwritten signature. I will not, at any time in the future, repudiate the meaning of my electronic signature or claim that my electronic signature is not legally binding.