Health Canada Santé Canada

CLINICAL TRIAL SITE INFORMATION FORM

A separate form for each clinical trial site must be completed by the sponsor and filed with the Health Products and Food Branch. **All fields must be completed prior to submitting this form to Health Canada.**

PART 1 - Clinical Trial Protocol Information

Please check one of the following:

Clinical Trial Application (CTA) ☐

Clinical Trial Application Amendment (CTA-A) ☒

1. Clinical Trial Protocol Title
A Phase I/II Trial of COX-2 Inhibitor, Celebrex™ (Celecoxib), [NSC# 719627] with Limited Field Radiation for Intermediate Prognosis Patients with Locally Advanced Non-Small Cell Lung Cancer, with Analysis of Prognostic Factors

2. Clinical Trial Protocol Number (if applicable)	3. Clinical Trial Control Number (if assigned)	4. CR file Number (if assigned)
0213	092335	9427-R1206-23C

PART 2 - Drug Product / Sponsor Information

A) Drug Product Information

5. Brand Name **Celebrex ®**

6. Proper or Common Name **Celecoxib**

B) Sponsor of Clinical Trial

7. Name of Sponsor (Full Name – No Abbreviations) Radiation Therapy Oncology Group

8. Street / Suite / PO Box	9. City / Town	10. Prov. / State	11. Country	12. Postal/ZIP Code
1818 Market Street, Suite 1600	Philadelphia	PA	USA	19103

Contact Person for Sponsor

13. Name	14. Telephone No.	15. Fax No.	16. Language Preferred
Wilma Hoffman	215-574-3162	215-574-0300	☒ English ☐ French

17. Title	18. E-mail
Director, Protocol Development & Regulatory Compliance	mmoore@phila.acr.org

C) Contact for THIS Clinical Trial

19. Contact Name	20. E-mail
Marcella Moore	mmoore@phila.acr.org

21. Company Name (Full Name - No Abbreviations)
Radiation Therapy Oncology Group

22. Street / Suite / PO Box	23. City / Town	24. Prov. / State	25. Country	26. Postal/ZIP Code
1818 Market Street, Suite 1600	Philadelphia	PA	USA	19103

27. Telephone No.	28. Fax No.	29. Language Preferred
215-574-3162	215-574-0300	☒ English ☐ French

PART 3 - Clinical Trial Site Information

A) Clinical Trial Site

30. Name of Site (Full Name - No Abbreviations)			
31. Street / Suite / PO Box	32. City / Town	33. Province	34. Postal Code
35. Commencement Date of Clinical Trial or Clinical Trial Amendment[1]			

B) Qualified Investigator

A Qualified Investigator Undertaking must be completed by the qualified investigator responsible for the conduct of the clinical trial at the site specified above. The completed undertaking must be retained by the clinical trial sponsor for a period of 25 years.

36. Name	37. Title		38. Language Preferred ☐ English ☐ French
39. Street / Suite / PO Box	40. City / Town	41. Province	42. Postal Code
43. E-mail		44. Tel. No.	45. Fax No.

C) Research Ethics Board Approval

A Research Ethics Board Attestation must be completed by the Research Ethics Board that reviewed and approved the protocol and informed consent form for this clinical trial at the site specified above. The completed attestation must be retained by the clinical trial sponsor for a period of 25 years.

46. Name of Research Ethics Board		47. Date of Approval	
48. Street / Suite / PO Box	49. City / Town	50. Province	51. Postal Code
52. Name of Contact Person	53. Telephone No.	54. Fax No.	55. Language Preferred ☐ English ☐ French
56. Title		57. E-mail	

1 Date of commencement of the trial: For the purpose of the Clinical Trial Site Information form – this is defined as the date when the clinical trial site is ready to enroll patients in the clinical trial. (Before a start date can be determined, both Health Canada and Research Ethics Boards approval must be obtained).