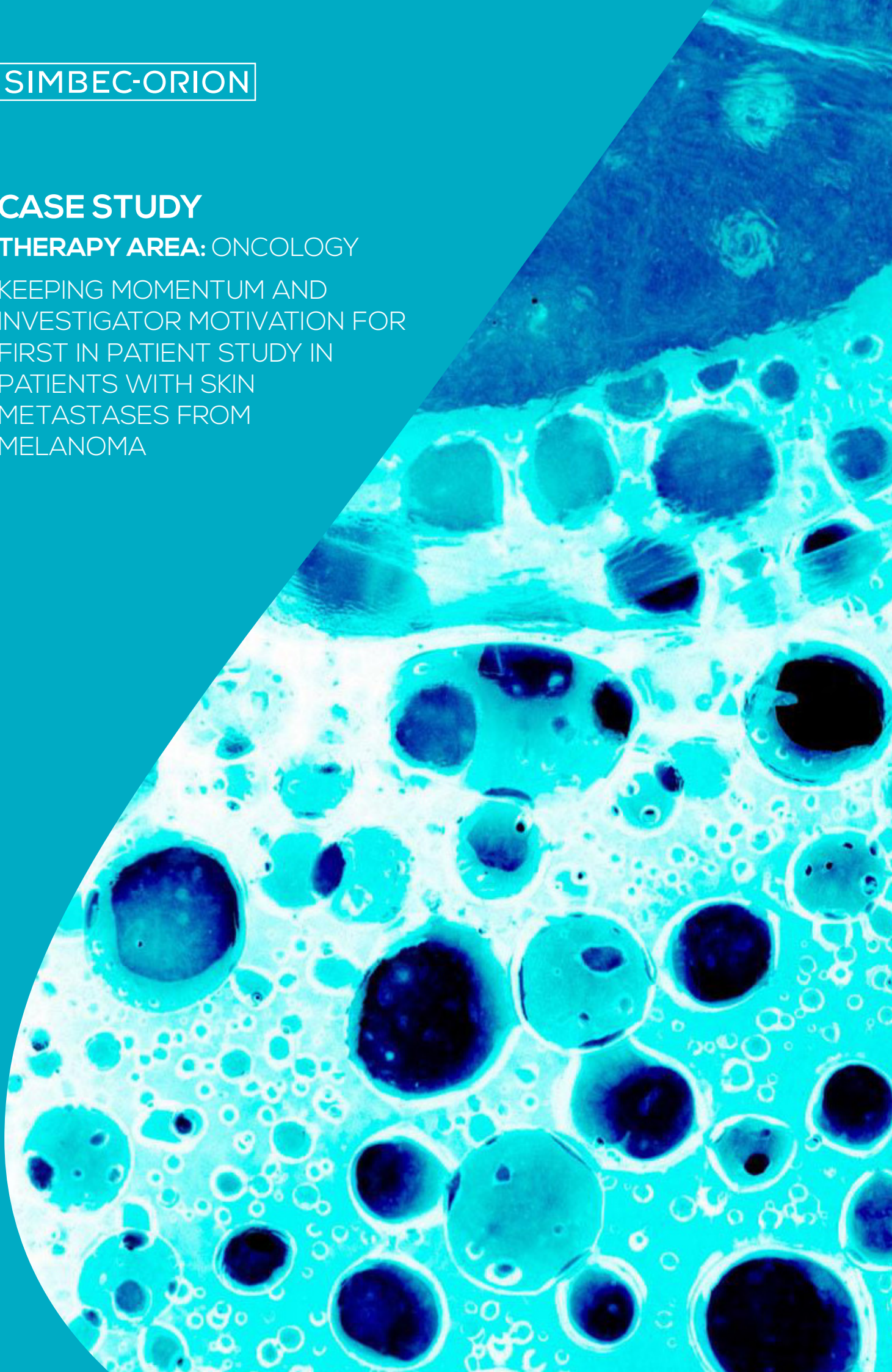
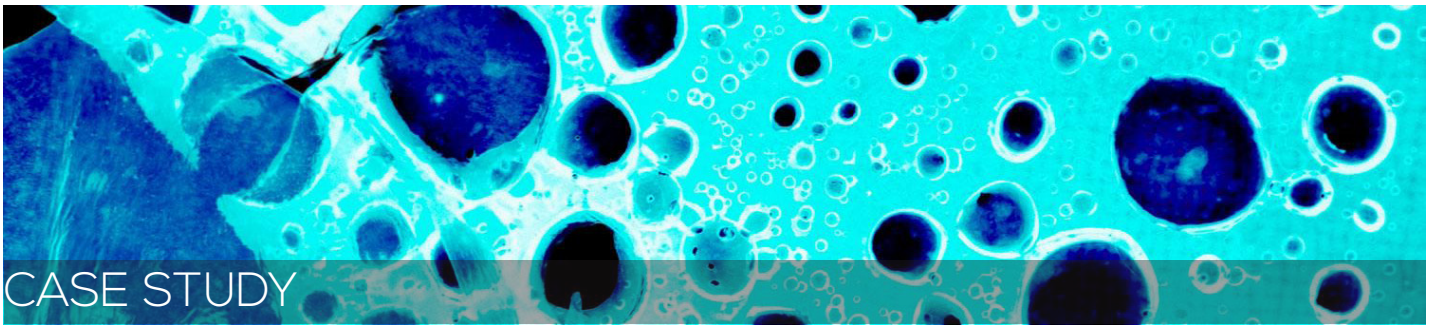
SIMBEC-ORION

CASE STUDY

THERAPY AREA: ONCOLOGY

KEEPING MOMENTUM AND INVESTIGATOR MOTIVATION FOR FIRST IN PATIENT STUDY IN PATIENTS WITH SKIN METASTASES FROM MELANOMA





CASE STUDY

FIRST-IN-HUMAN PHASE I STUDY OF THE DNA REPAIR INHIBITOR (STUDY DRUG) IN COMBINATION WITH RADIOTHERAPY IN PATIENTS WITH SKIN METASTASES FROM MELANOMA

SPONSOR OBJECTIVES:

Our client needed to work with motivated investigators to rapidly identify and enrol patients to determine the safety of their study drug in combination with radiotherapy, to evaluate the safety and tolerability profiles of (study drug) in combination with radiotherapy and concomitant dosing of chloroquine, (according to the National Cancer Institute Common Terminology Criteria for Adverse Events).

- To determine the Dose Limiting Toxicities (DLTs), the Maximum Tolerated Dose (MTD) and the Recommended Dose (RD) of (study drug) in combination with radiotherapy and concomitant dosing of chloroquine
- To determine the pharmacokinetics (PK), parameters of (study drug), to evaluate the preliminary anti-tumor activity and the pharmacodynamic effect (including biomarkers) of (study drug)

CHALLENGES OF THE STUDY

First-In-Human Phase I study using study drug in combination with radiotherapy.

- To Admin route
- To inclusion exclusion critera

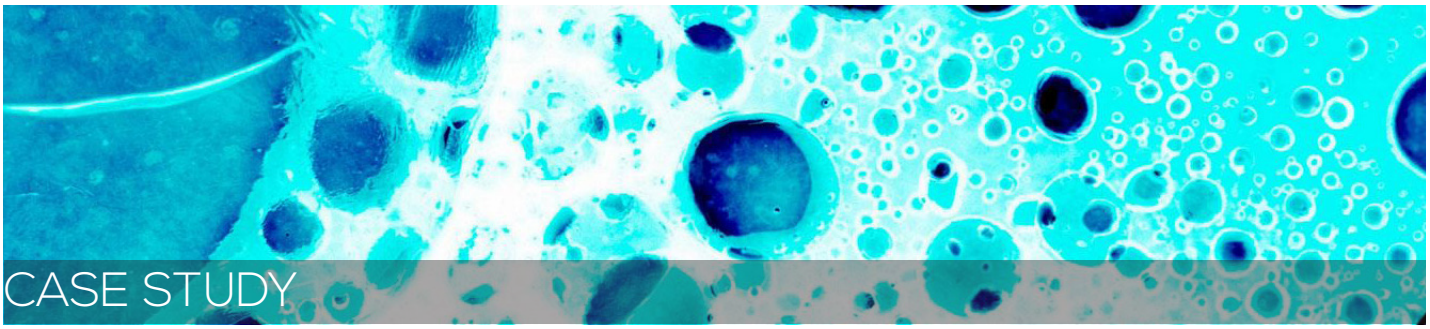
} Mid Study

PATIENT PROFILE

- Male and female patients aged 18 + years with histologically-confirmed metastatic melanoma with relapsed cutaneous tumors, including locally advanced melanoma-in-transit
- Patients with at least two tumors of measurable size, (≤ 4cm in largest diameter).

DRUG TYPE

First in class investigational drug.



CASE STUDY

STUDY CHALLENGES:

The key challenge with any First-In-Human Patient study is patient recruitment. Key to the success of the study was the motivation of the investigators, who were selected by a National Coordinator from a National Oncology Centre. This focus ensured motivation using a centralised coordinated approach for a First in Patient oncology study. Visibility amongst sites on recruitment status kept motivation and engagement to drive the study.

The route of administration for the IMP changed mid study as well as inclusion criteria.

OUR SOLUTIONS:

Simbec-Orion was in charge of protocol writing, and all key recruitment and study documents for ethics and for regulatory submission. We also set up the Drug Safety Monitoring Board (DSMB) for the dose escalations, ensuring that we mitigated challenges around dose escalation.

Project management from Simbec-Orion was key in keeping momentum and communication between all sites to demonstrate how they were tracking to targets and the project as a whole team – this mid study protocol amendment was managed efficiently, it was important to keep sites updated and to continue to identify patients in parallel, whilst the protocol change went through, in order to keep patients lined up to be consented on the new protocol without slowing down enrolment.

RESULT FOR CUSTOMER:

- The sponsor was able to meet their scientific objectives, which resulted in this First-in-Patient, first-in-class trial, showing that the (study drug) can be safely used in patients in combination with radiotherapy.
- Preliminary results suggested that the combined treatment increases radiotherapy efficacy and sponsor was able to meet their commercial objectives to further develop their compound.
- Achieved in timelines set by client.

Number of countries:	Number of sites:	Number of completed patients:	Study completion:
01 (FRANCE)	12	23	40 MONTHS FROM STUDY START TO FINAL REPORT

SIMBEC-ORION

MISSION STATEMENT

We are Simbec-Orion. An international, full service, boutique CRO; growing by bringing together the best possible people, healthcare professionals and drug developers, from all areas of clinical development.

We focus on a defined series of core therapeutic areas, where we can make best use of our skills elegantly to design, execute and deliver our clients' clinical development needs.

We are making Simbec-Orion a highly respected and profitable boutique CRO. We do this by working for our clients with excellence, commitment and passion for our trade. We provide an environment in which our colleagues can continue to grow and develop.

We will always remember that our work leads to the improvement of patients' lives

To find out how Simbec-Orion can help with your clinical development program email **info@SimbecOrion.com**

Or call our business development team on **+44 1753 578080**

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FRONT COVER IMAGE:
CANCER CELLS