



# Philips-Led European Oncology Project Integrating Molecular Testing, Liquid Biopsy, Medical Imaging

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## *Premium*

NEW YORK (GenomeWeb) – A new European initiative led by Royal Philips promises to deliver multiple new tests and methods for improving the treatment of breast cancer and rectal cancer.

Philips [announced the project](#), called "Liquid Biopsies and Imaging for Improved Cancer Care" (LIMA), last month. Backed with €6.3 million (\$7.5 million) in EU Horizon 2020 funding, the effort will commence in January and run for four years. The project aims to apply liquid biopsies, molecular tests, and magnetic resonance imaging (MRI) during the early stages of cancer treatment.

Researchers at University Medical Center Utrecht in the Netherlands and the Institut National de la Sante et de la Recherche Medicale (INSERM) in France are taking part in LIMA, as are Philips, Agena Bioscience, DiaDx, Stilla Technologies, Angle, and ALS Automated Lab Solutions. Each of LIMA's commercial participants stands to benefit from its inclusion.

"It certainly is the aim that new technological approaches and tests in liquid biopsies and MRI-based feature analysis, and possibly their combination, developed as part of the LIMA project, will be made available for clinical use," said Hans Hofstraat, innovation program manager at Philips.

"Every partner will be responsible for the commercial development of [its] own products," Hofstraat added. He noted that some participants, such as Agena Bioscience, already have achieved CE-IVD marks for their platforms, "demonstrating the commitment of the partners involved" to the effort.

Founded in the Netherlands in 1891, Amsterdam-based Philips has intensified its healthcare focus in recent years. Last year it spun off its lighting division to turn its attention to healthcare and has made multiple investments in imaging and data analysis this year, most recently snatching up clinical informatics firm Forcare for an undisclosed sum earlier this week.

Hofstraat said that within Philips Research, the company's private research organization based in nearby Eindhoven, oncology is a "key area of focus" where Philips is keen to combine its expertise in imaging with molecular testing. Hence the reason the firm organized LIMA.

"We believe that imaging, part of the gold standard to diagnose cancer and monitor therapy response, will continue to play a key role in the future," said Hofstraat. "Yet with the increasing role of genomic information from tissue samples ... or liquid biopsies from blood samples, gradually entering routine disease management, we expect additional roles of imaging in disease localization and characterization," he said.

Within LIMA, Philips seeks to determine how results from these different diagnostic modalities might fit together, as well as how results might be delivered to improve patient outcomes.

"Due to the multitude of diagnostic options in the liquid biopsy domain, we think a consortium bringing all these technologies together is the best way forward," said Hofstraat. "It allows a cross-modality combination of diagnostic data from the same patient, of imaging and liquid biopsy data."

Philips own role in LIMA is as its coordinator and instigator. Philips will also act as LIMA's liaison to the European Commission. Hofstraat said the firm will have responsibilities in three data integration areas: developing MRI protocols and interpretation of MRI features together with UMC Utrecht; analyzing circulating DNA and circulating tumor cells obtained by liquid biopsies with several partners; and creating data-analysis tools for combining imaging and liquid biopsy results.

"In the LIMA project, our expertise in both MRI image acquisition and image analytics, and in cancer pathway analysis will be applied," said Hofstraat. All of this is in line with the company's goal to bring new offerings to the clinical market, he noted.

"One could envision that in the oncology domain, where clinicians are and increasingly will be using a combination of radiology, pathology, genomic tests, and liquid biopsy tests to arrive at their treatment plan, the need for a solution — not just single products — will become important," said Hofstraat.

LIMA plans to determine how to best accomplish that for optimal patient care.

"This may well lead to new, next-generation or combined tests," said Hofstraat, "but the first step will be to investigate in a clinical setting how to best combine these approaches."

### **Commercial potential**

Of the other companies participating in LIMA, three — DiaDx, Stilla, and Agena — are providing platforms for testing cells obtained via liquid biopsies for certain oncology-linked markers. Angle and ALS Automation Lab Solutions meantime will provide tools for isolating CTCs and single CTC detection and selection, respectively.

"LIMA's plan is to combine all of these techniques so that as soon as you are circulating DNA-positive, you go to imagery right away, directly looking for tiny tumors. That's the point," said Alain Thierry, research director at INSERM. As part of LIMA, Thierry will lead efforts to study the potential of circulating DNA in localized advanced cancer with the assistance of imaging techniques in patients undergoing early-stage treatment.

"The first potential of circulating DNA is to detect mutations," said Thierry. "Liquid biopsies allow us to follow up the patients," he said. "You can control the treatment and you can guide the clinician in the choice of using adjuvant therapy or not, and make surveillance of the recurrence of the tumor," he said. "You can also screen for cancer. So there is a lot of potential here."

Thierry is also the co-founder of DiaDx, a Montpellier, France-based company that has commercialized IntPlex, a quantitative PCR-based approach for detecting cancer-associated mutations in circulating DNA. Thierry remains a scientific consultant for the company.

When asked about the way LIMA might impact DiaDx's product pipeline, Thierry replied that, "You cannot commercialize a standard of care. You cannot commercialize a strategy for cancer management." However, participating companies like DiaDx might seek to protect and commercialize tests to detect and characterize circulating tumor cells.

"Especially by evaluating the technologies together, there will be patents for sure, but these patents will be owned by the particular companies," said Thierry. "If a better way to use imaging parameters in combination with circulating DNA [is developed], it will be patented as well, by Philips," he said.

Another company taking part in LIMA is Villejuif, France-based Stilla, which has commercialized a digital PCR platform called the Naica System, with which it hopes to support molecular testing.

CEO Rémi Dangla said that with LIMA, Stilla has the opportunity to develop color-based liquid biopsy assays with 10 or more distinct targets per panel. Stilla is also in the midst of introducing a six-color detection system, which will improve its multiplexing capabilities, Dangla said.

"This will be key in this study, because we will be looking at cancer patients that have not been characterized by [next-generation sequencing]," Dangla noted. "We need to have panels that are sufficiently broad that we can detect meaningful markers for a vast majority of patients," he said. "This will be the first study where we use this system to provide high-plex assays," Dangla added, "so this will be a very convincing proof of concept."

Given LIMA's focus on breast cancer and rectal cancer, Stilla has the opportunity to develop and validate two panels, Dangla said, both of which will be tested on patient samples. "For us as a company, if the panels are successful, we'll probably make the decision to sell the assays too."

Agena is also eyeing commercial opportunities related to the project. The San Diego-based company said its mass spectrometry-based MassArray system will be used to provide molecular genetic information from liquid biopsies during LIMA's research activities. Using MassArray, users can detect over 50 variants from a blood sample.

"Because this study is focused on the characterization of primary breast cancer and rectal cancer, the panel that will be created on the MassArray certainly may be considered for commercialization, pending the results of the study," said Mickie Henshall, vice president of marketing.

That being said, Henshall stressed that as the oncology field evolves, many of its customers opt to develop their own tests, rather than buy fixed panels. Therefore, Agena sees LIMA as an avenue to "further demonstrate the benefits of the technology" for creating these custom panels for use in clinical oncology in Europe and beyond.

Agenda [achieved a CE-IVD mark](#) for a version of its platform called MassArray Dx in June. The company maintains a subsidiary in Hamburg, Germany, that is officially taking part in LIMA.

Angle and ALS Automation Lab Solutions might also develop new products based on their work with LIMA. Angle CEO Andrew Newland said in a company statement that his firm will work with Philips and the other commercial partners in LIMA on the "development of new biopsy solutions" as well as the "joint commercialization of these solutions" in the future.

The Guildford, UK-based liquid biopsy company has commercialized its Parsortix system for capturing cells circulating in blood and harvesting them for analysis. Parsortix will be the sole system used for harvesting CTCs in LIMA, according to the firm. Angle reported that it will receive £0.4 million (\$0.5 million) for its participation in LIMA over the next four years.

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