



PICCOLO

Multimodal highly-sensitive PhotonICs endoscope for improved in-vivo COLON Cancer diagnosis and clinical decision support

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Promotional material		

Abstract:

This document represents the Deliverable 8.3 in the framework of the PICCOLO project. The document describes various promotional material that has been generated, including leaflets and press releases.

Dissemination level		
PU	Public	X
CO	Confidential, only for members of the consortium and the Commission Services	



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Documents history

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V0.1	25/07/2017	Starting version, template
V0.2	25/07/2017	Definition of ToC
V0.3	25/07/2017	First complete draft
V0.4	25/07/2017	Integrated version (send to WP members)
V0.5	25/07/2017	Updated version (send to Quality Manager)
V0.6	25/07/2017	Updated version (QM send to project internal reviewers)
Sign off	25/08/2017	Signed off version (for approval to EB members)
V1.0	25/08/2017	Approved Version to be submitted to H2020 office

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Executive summary

This document represents the Deliverable D8.3 in the framework of the PICCOLO project, titled “Multimodal highly-sensitive PhotonICs endoscope for improved in-vivo COLOn Cancer diagnosis and clinical decision support” (Project Acronym: PICCOLO; Call: ICT-29-2016: Photonics KET 2016; Topic: H2020-ICT-2016-2017).

In this document, produced in month 6 of the PICCOLO project, initial promotional material has been generated. In addition to the website and Twitter accounts, delivered in D8.2, leaflets for conferences and leaflets for patients have been designed. Press releases in English, Spanish and Basque have been written, and have been published in many sites on the internet. An updated version of this deliverable will be submitted in month 30, which will present further material based on the results of the project.

1. Introduction

Objective of this document

This document represents the Deliverable D8.3 in the framework of the PICCOLO project, titled “Multimodal highly-sensitive PhotonICs endoscope for improved in-vivo COLOn Cancer diagnosis and clinical decision support” (Project Acronym: PICCOLO; GA 732111).

The document gives a description of leaflets and press releases that have been designed to promote the project to the general public, and provide information to patients about what the advantages of the Piccolo probe will be. This will increase awareness of the project among academic and medical persons, as well as patients who may undergo treatments involving the Piccolo endoscope probe.

Structure of this document

This document consists of three sections. The first section is the introduction of the document and its aims, its structure and the relationship with other deliverables of the PICCOLO project. After the introduction, we find the main part of the document, consisting of Section 2 describing the material which is being used to promote the project, followed by a summary of the material.

Relationships with other deliverables

Deliverable 8.3 presented in this document relates on the following deliverables:

- D8.1 “Plan for the Exploitation and Dissemination of Results (PEDR)”. The PEDR is a strategic document for the beneficiaries helping them to establish the bases for their intellectual property strategy, dissemination and exploitation activities.
- D8.2 “Website, templates and social media”. Establishing a presence on the internet that is publically available.

2. Promotional material

The following sections present current material that exist either in physical form (leaflets), or that have been published on the web (press releases).

2.1 Leaflet for conferences

In order to promote the piccolo project at conferences, the leaflet below was designed. This is to be printed in A5 format, and follows the visual and font styles that are also used in Powerpoint presentations, as set out in D8.2. If a consortium member presents a poster at a conference, it is intended that there is a pocket at the side of the poster containing these leaflets so that interested parties can take leaflets away with them. If a consortium member presents a talk, that person can bring these leaflets and distribute them to any interested party.

NOTE: This conferences leaflet is a draft, a reviewed update is expected in the following months

PICCOLO

PICCOLO brings together European scientists and clinicians to create an endoscope probe to better diagnose bowel polyps and early colon cancer.

Advanced technology
The proposed compact, hybrid and multimodal photonics endoscope is based on Optical Coherence Tomography (OCT) and Multi-Photon Tomography (MPT) combined with novel red-flag fluorescence technology for in-vivo diagnosis and clinical decision support.
This innovative endoscope will provide high-resolution information, giving details of the changes occurring at the cellular level.

Improved diagnosis
By combining the outstanding structural information from OCT with the precise functional information from MPT, the new endoscope will provide gastroenterologists with immediate and detailed in-situ identification of colorectal neoplastic lesions and facilitate accurate and reliable in-vivo diagnostics, with additional grading capabilities for colon cancer as well as in-situ lesion infiltration and margin assessment.
This will significantly impact clinical practice allowing in vivo optical biopsy assessment via the automatic analysis of images.

Patient and surgeon benefits
Early, accurate diagnosis and precise intervention can increase cure rates by up to 90%.

The new endoscope aims to provide:

- 3D images to diagnose non-cancerous polyps, pre-cancerous polyps and early colon cancers
- non-destructive imaging under tissue surface to identify internal polyp structure
- valuable information as to the polyp type

This will lead to:

- Fewer invasive surgery procedures
- less discomfort for patients
- less time necessary for accurate diagnosis
- reduced costs through compact instrumentation

Outlook
PICCOLO will provide a new approach in colon cancer detection, and in time, the new image based diagnosis methods could be applied to diseases in other organs of the body.
The team aim to have the first prototype refined by the end of 2018 with clinical trials to begin around 2020.

www.piccolo-project.eu
info@piccolo-project.eu

Figure 2.1.1: Leaflet for conferences, front side.




Figure 2.1.2: Leaflet for conferences, reverse side.

2.2 Leaflet for patients

A leaflet aimed at promoting the project to colonoscopy patients has been prepared. This is to be printed in A4 size, front and back, and is to be folded in half to produce a leaflet A5 in size, giving four pages in total. These are intended for hospitals and doctor's surgeries where the doctor or colonoscopist can explain to the patient what the procedure will be, and how it will be beneficial for them. The patient can take this leaflet away and read it in their own time.



Figure 2.2.1: Leaflet for patients, back and front of folded leaflet.

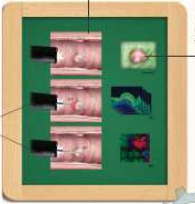
.....PICCOLO  me

Purpose of this study*

- ▶ Your colonoscopy will check for the presence of polyps that will be removed and sent to a lab to test whether or not it carries a risk of developing into cancer.
- ▶ The PICCOLO probe will try to differentiate whether polyps have or not a risk of developing into cancer (future help to clinicians for not removing harmless polyps).
- ▶ The PICCOLO probe will be only used to gather information (no decision about your treatment or care will be made with this new system).

What is PICCOLO?

- 1 IT LOSES LOSE LIGHT AND TWO DIFFERENT TYPES OF MICROSCOPE TECHNOLOGIES THAT DO NOT CAUSE ANY DAMAGE TO THE TISSUE, BUT ARE CAPABLE TO HIGHLIGHT SHAPES OF CELLS AND THEIR ACTIVITY.
- 2 A NEW ENDOSCOPIC SYSTEM THAT PRODUCES MICROSCOPIC IMAGES.
- 3 THE PICCOLO PROBE REVEALS THE STRUCTURE OF CELLS TISSUE AND SOME OF ITS FUNCTIONS.



How does it work?

- ▶ After the standard colonoscopy, the PICCOLO probe will examine the piece of tissue before it is sent to the lab for standard examination and diagnosis.
- ▶ Your colonoscopy will be exactly the same as patients who do not participate in this study (no additional tissue samples or procedural time will be required).
- ▶ Your colonoscopy will be anonymously video recorded to compare video images with PICCOLO data.

(*) The study has been approved by Ethics Committees

Why me?

- 1 YOU HAVE ATTENDED THE HOSPITAL FOR A COLONOSCOPY WHERE THE ENDOSCOPIST WILL CHECK FOR THE PRESENCE OF POLYPS.
- 2 WE WOULD LIKE TO GATHER IMAGES OF A VARIETY OF POLYPS TO CHECK THE PICCOLO
- 3 ENTIRELY VOLUNTARILY PARTICIPATION IN THE PICCOLO STUDY, WITH POSSIBILITY OF WITHDRAWAL AT ANY TIME.

What about my colonoscopy?

- ▶ Standard colonoscopy: no additional pain or recovery period, same routine procedure, same diagnosis and treatment process.
- ▶ Nothing to do, more than approve the collection of images with the PICCOLO probe from tissue already removed.
- ▶ Video recorded and PICCOLO data will be used to research future assessments of any polyps (completely anonymised, you will not be identifiable).
- ▶ The removed tissue could be stored in a biobank for research projects.

What about my data?

- ▶ Any images acquired during your colonoscopy would help us to reach the PICCOLO study goals.
- ▶ You can be informed about published research results if you wish.
- ▶ Confidentiality rules will be maintained.
- ▶ You will not receive any payment for your involvement in this study neither benefits from any inventions.




Figure 2.2.2: Leaflet for patients, inside left and right pages of folded leaflet.

NOTE: The patient leaflet is a draft, a reviewed update is expected in the following months

2.3 Press release

In order to promote the project via the internet, three press releases have been prepared, in English, Spanish and Basque languages.

2.3.1 English version

In order to promote the project in English speaking national and international press, the following press release was released to the media. This is freely available on the project website at <http://www.piccolo-project.eu/publications-presentations/publications/>

New endoscope to target colon tumours

Minimally invasive endoscope using breakthrough photonics technology to enable rapid, accurate diagnosis of bowel polyps and early colon cancer. Funded under Horizon 2020, the EU's research and innovation programme, a European group of scientists are working on the development of an innovative, compact and easy to use endoscopic device, which will play a crucial role in identifying

and diagnosing pre-cancerous polyps and early colon cancers. Worldwide, colon cancer remains the third most common cancer in men, behind lung and prostate cancer, and second in women, behind breast cancer. Colorectal cancer ranks as one of the world's most predominant cancers, affecting approximately one in ten people during their life and causing almost 700,000 annual deaths globally. Almost 95% of these cases are adenocarcinomas, which typically start as a growth of tissue called a polyp. Today, the main method to achieve early detection of the disease is colonoscopy. While up to 40% of the patients under routine analysis colonoscopy present one or more polyps, almost 30% of these polyps are not detected, especially in the case of flat polyps. Of those detected, 29-42% are generally hyperplastic, and will not develop into cancer. The remainder are neoplastic polyps, which are of primary importance because they harbor malignant potential and represent a stage in the development of colorectal cancer. For this reason, it is essential to identify these polyps at an early stage. Speaking about the PICCOLO Project Dr. Artzai Picon (Tecnalia) said "We hope that PICCOLO will provide major benefits over traditional colonoscopy. Firstly, by developing an advanced endoscope, using both Optical Coherence Tomography (OCT) & Multi-Photon Tomography (MPT), we will provide high-resolution structural and functional imaging, giving details of the changes occurring at the cellular level comparable to those obtained using traditional histological techniques. Furthermore, when multiple polyps are detected in a patient, the current gold standard procedure is to remove all of them, followed by microscopic tissue analysis. Removal of hyperplastic polyps, which carry no malignant potential, and the subsequent costly histopathological analysis might be avoided through the use of the PICCOLO endoscope probe, which could allow image-based diagnosis without the need for tissue biopsies". The long term potential for this project is exciting. Not only will it provide a new approach in colon cancer detection, but the new image based diagnosis methods could be applied to diseases in other organs of the body. The PICCOLO team hope to have refined their first prototype by the end of 2018 and targets clinical trials to begin around 2020.

This was picked up at many outlets, which will be listed in the next version of D8.1.

2.3.2 Spanish press release

A press release was also prepared in Spanish, and was released to Spanish media.

Un endoscopio fotónico para la mejora del diagnóstico del cáncer de colon

El Centro de Cirugía de mínima Invasión Jesús Usón (CCMIJU) ha asistido, durante los días 18 y 19 de enero, a la reunión de lanzamiento y puesta en marcha del proyecto europeo “Multimodal highly-sensitive PhotonICs endoscope for improved in-vivo COLOn Cancer diagnosis and clinical decision support” (PICCOLO, por sus siglas en inglés), que se ha celebrado en Bilbao.

Dicho proyecto tiene como objetivo desarrollar un endoscopio fotónico compacto, híbrido y multimodal basado en tomografía de coherencia óptica y multifotónica, combinado con fluorescencia. El cáncer colorrectal representa alrededor de un 10% de todos los cánceres del mundo, por tanto un diagnóstico temprano y preciso puede aumentar su curación hasta en un 90% de los casos.

Un equipo multidisciplinar europeo, formado por la Fundación Tecnalia, líder del proyecto, y otros ocho socios europeos procedentes de Italia, Reino Unido, Irlanda, Alemania y España, entre ellos el CCMIJU, se han unido para llevar a cabo este ambicioso proyecto europeo, financiado por el programa Horizonte 2020 de la Unión Europea. PICCOLO persigue desarrollar un endoscopio innovador para proporcionar a los gastroenterólogos una identificación in situ, inmediata y detallada de las lesiones neoplásicas y facilitar diagnósticos precisos y fiables.

Todo ello redundará, como indica el Dr. Sánchez Margallo, investigador principal y Director Científico del CCMIJU, en la mejora de la calidad de vida de los pacientes, pues este proyecto incluye toda la cadena de valor, con socios preclínicos (la institución cacereña) y clínicos, proveedores de tecnología, PYMEs fotónicas y empresa líder en el mercado de endoscopia.



Este proyecto ha sido financiado por el programa de investigación e innovación de Horizonte 2020 de la Unión Europea con número 732111.

Esta información refleja el punto de vista de la institución, por tanto se exime a la Comisión europea y/o a sus Agencias de la responsabilidad del uso que se haga de la información aquí contenida.

This press release was also picked up at many Spanish outlets, and will be listed in the next submission of D8.1.

2.3.3 Basque press release

The following press release has also been prepared and will be released shortly in Basque media.

EUSKADI INVESTIGA UN NUEVO ENDOSCOPIO QUE MEJORARÁ EL DIAGNÓSTICO DEL CÁNCER DE COLON Y RECTO

- El Hospital Universitario Basurto participa en el proyecto PICCOLO dirigido por Tecnia cuyo objetivo es desarrollar un endoscopio que permita un diagnóstico temprano del cáncer colorrectal mediante técnicas avanzadas de toma de imágenes de la lesión
- Sin necesidad de tomar biopsias o extirpar el pólipo, el endoscopio ayudará a determinar en tiempo real si un pólipo es benigno, pre-maligno o si ya ha evolucionado a cáncer ("biopsia óptica")
- Permitirá un diagnóstico seguro y preciso sin causar daño al paciente
- El Gobierno Vasco trabaja por lograr un diagnóstico seguro y precoz del cáncer. El Programa de Detección Precoz de Cáncer Colorrectal de Osakidetza es ya reconocido como **uno de los mejores programas poblacionales preventivos de cáncer colorrectal del Estado y a nivel internacional**

El cáncer colorrectal es el tipo de cáncer más frecuente en la CAPV si se consideran ambos sexos en conjunto. La mortalidad asociada es alta si se detecta en una fase avanzada. La mayoría de los cánceres se desarrollan a partir del lento crecimiento de lesiones premalignas como algunos pólipos y representa alrededor de una décima parte de todos los casos de cáncer a nivel mundial.

El Departamento de Salud del Gobierno Vasco trabaja por lograr un diagnóstico temprano y riguroso y una intervención de precisión ya que así se puede aumentar la tasa de cura a un 90%. En este sentido, el Programa de Detección Precoz de Cáncer Colorrectal de Osakidetza completó este mes de marzo la invitación al 100% de las personas en segunda vuelta y constituye uno de los mejores programas poblacionales preventivos de cáncer colorrectal del Estado y también a nivel internacional en términos de cobertura, calidad y participación. **Las personas entre 50 y 69 años es el grupo de población** al que va dirigido. A finales de este año habrá conseguido haber invitado al 80% de las personas por tercera ronda.

La lucha contra el cáncer de colon requiere de técnicas de diagnóstico mejoradas con suficiente precisión que permitan una evaluación de la lesión de forma rápida, precisa e in situ, así como la extirpación de lesiones durante las intervenciones de la práctica clínica. La eficacia en la prevención del cáncer colorrectal depende de la identificación y de la extirpación completa de todas las lesiones pre-malignas. La colonoscopia es la prueba principal utilizada, pero hasta el 30% de los

pólipos pueden escapar a su detección. Por otro lado el 29-42% de los pólipos identificados no son pre-malignos y no derivarán en cáncer, pero actualmente no es posible diferenciarlos con confianza de los que sí los son.

En este contexto, Euskadi está trabajando en un proyecto de investigación que proporcionará un avance sobre la colonoscopia que actualmente se realiza en la práctica asistencial. El proyecto se llama PICCOLO y se desarrolla a través de un consorcio europeo formado por los Servicios de Digestivo y Anatomía Patológica del Hospital Universitario Basurto con el apoyo del Biobanco Vasco de la Fundación Vasca de Innovación e Investigación Sanitarias-BIOEF (instrumento creado por el Departamento de Salud para promover la innovación y la investigación en el sistema sanitario de Euskadi) y coordinado por el centro de investigación y desarrollo tecnológico Tecnalía, coordinadores del proyecto. En este proyecto, financiado por la Comisión Europea con 4 millones de euros y que durará 36 meses, participan 9 socios más del Estado, Italia, Irlanda, Alemania e Inglaterra.

Se espera que PICCOLO proporcione un avance sobre la colonoscopia que actualmente se realiza en la práctica asistencial. Cuando se detectan múltiples pólipos en un paciente, el procedimiento estándar actual es eliminar todos ellos y realizar posteriormente, un análisis microscópico del tejido.

El proyecto busca desarrollar un endoscopio que utilice técnicas de diagnóstico avanzado in situ durante la endoscopia, a través de toma de imágenes que analicen con precisión cómo es la estructura de la lesión y cómo funciona y se desarrolla. Asimismo, el endoscopio permitirá la detección automática de lesiones sutiles que se suelen escapar (como lesiones de morfología plana y aspecto similar a la mucosa normal del colon) gracias al uso de fluorescencia en una colonoscopia con imagen de alta resolución.

El objetivo final será desarrollar un nuevo colonoscopio que permitiría a los y las profesionales del sistema sanitario conocer mejor el diagnóstico de la lesión sin necesidad de tomar biopsias o extirpar el pólipo, diferenciar en tiempo real si este es benigno, pre-maligno o si ya ha degenerado a cáncer ("biopsia óptica"). Además podrá ayudar en la extirpación completa de los pólipos al permitir una mejor evaluación de sus márgenes de la forma y composición. En un futuro el objetivo posterior será aplicar esta tecnología para el diagnóstico de enfermedades en otros órganos

PICCOLO utilizará en una primera fase modelos animales representativos de humanos para generar biomarcadores de imagen que permitan una detección y caracterización. Se espera tener el primer prototipo para finales del 2017 y apunta hacia el año 2020 para que comience su comercialización.

La extirpación innecesaria de estos pólipos no malignos conlleva un aumento del riesgo para los pacientes (sangrados, perforación), una mayor duración de la colonoscopia, así como un aumento en la carga de trabajo para el Servicio de Anatomopatología y mayores costes. Por esta razón, es esencial identificar los pólipos malignos en una fase temprana y PICCOLO aportará importantes avances en este campo.

3. Conclusion/Further work

In this document, produced in Month 7 of the PICCOLO project, promotional material has been generated. In addition to the website <http://www.piccolo-project.eu/> and Twitter accounts https://twitter.com/piccolo_eu, described in D8.2 and submitted to the Commission in Month 3, leaflets for conferences and leaflets for patients have been designed to further the public awareness of the project. Press releases in English, Spanish and Basque have been written, and have been published in many sites on the internet.

Further work will involve a leaflet for doctors, so that doctors not involved directly with the project can understand the benefits of the new probe, further increasing the widespread adoption of the new technology, and a banner for posters that can be presented at conferences. In Task 8.3, the project will be promoted through training sessions and clinical workshops, which will require further material to be disseminated to the public and to clinicians. This will include summary data and results from the project, showing the increased diagnostic capability of the developed endoscope probe.

The timeline for the generation of this further promotional material is as follows:

Leaflet for doctors/clinicians, Month 12

Banner for conferences, training sessions and workshops, Month 12

Updated Banner for conferences, training sessions and workshops, Month 24

Brochure of key results, suitable for a technical audience, Month 24

Brochure of key results, suitable for a general audience, Month 24

Brochure of expected product, Month 30

Second deliverable submission, D8.3b, Month 30