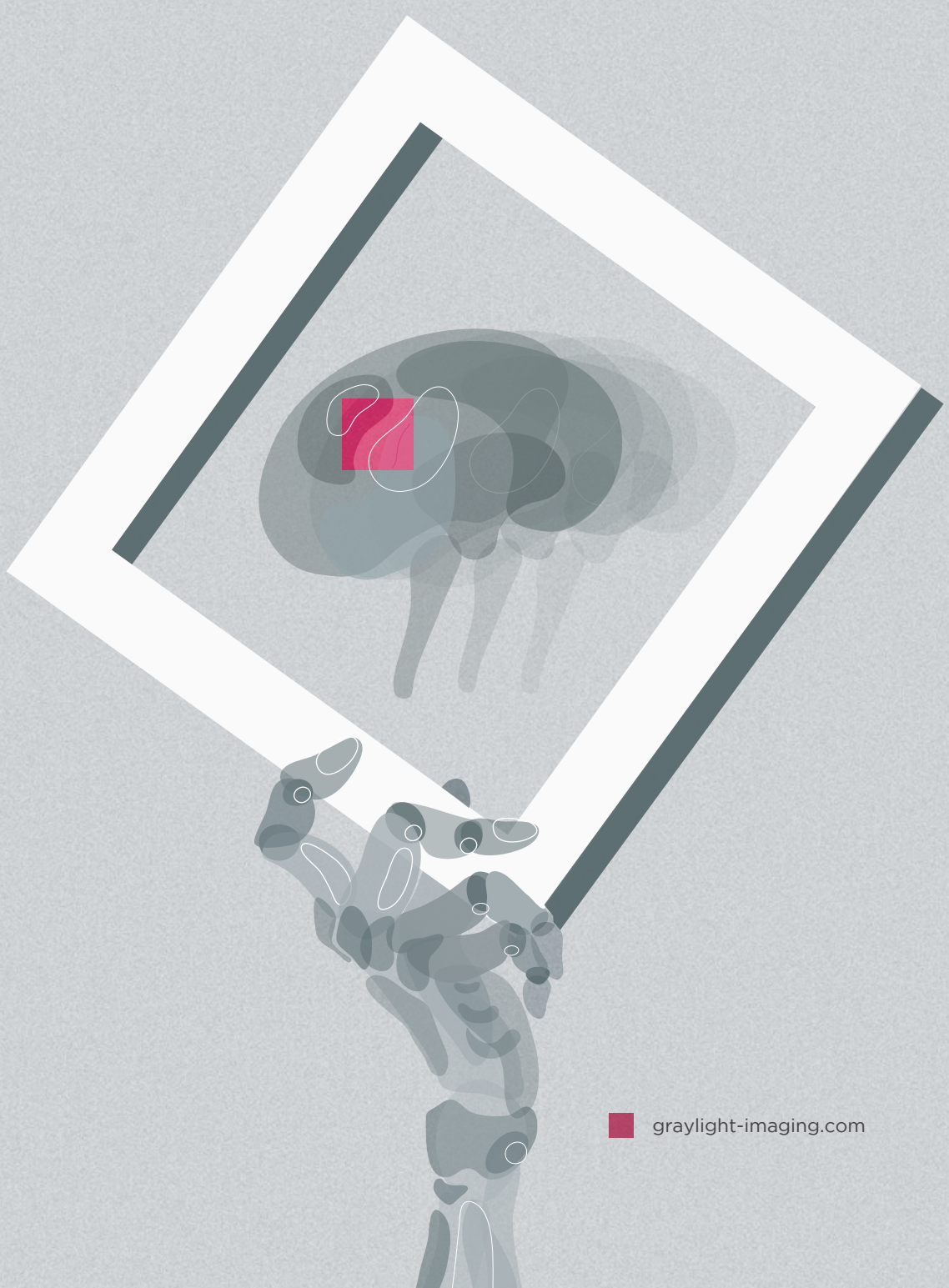
GRAYLIGHT
MEDICAL IMAGING SOFTWARE

Lessons Learnt

Certified medical product development



We’re experts in software development requiring certifiaction

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Table of contents

Project specifications

ITEM	DESCRIPTION
Technologies	Python, C++, TensorFlow, Keras, deep learning, machine learning, medical image computing analysis
Industry	Healthcare
Project type	R&D
Project duration	46 months
Team	There were two sub-teams: research team and development team. The research (scientific) team dealt with design and analysis of the algorithms. It consisted of experienced scientists (people with doctorate in natural or technical sciences). The development team consisted of experienced software engineers and worked on the implementation side of the end product.

Project objective

Within the frames of this project we were developing methods for analysis of brain examinations performed using magnetic resonance imaging (MRI) datasets.

These methods were supposed to enable accurate segmentations as well as convenient processing of large and difficult medical image datasets that can come as streams or be of different qualities. The goal of the project was to increase the diagnostic power, improve the effectiveness of diagnosis of glioblastoma patients and to objectively measure the volume of the lesion. The project was being realized in tight cooperation with the Cancer Center and Institute of Oncology in Gliwice, Poland.

THE PROJECT WAS BEING REALIZED IN TIGHT COOPERATION WITH THE CANCER CENTER AND INSTITUTE OF ONCOLOGY IN GLIWICE, POLAND.

Project evaluation /clinical assessment

The aim was to validate the segmentation made by the AI model. The results were presented in the form of DICOM files of the original

study with the outline of the area recognized by the system as a lesion (oedema) caused by glioma. The participants of the study were radiologists from two different centres, with at least 1 year of experience in imaging diagnostics, which was one of the criteria for admission. We gathered a group of 12 radiologists with 3 to 11 years of professional experience and asked each of them to evaluate independently 130 segmentations on a scale of 1 to 4, where the individual numbers corresponded to the statements:

Very low-quality segmentation
I would not use the result in the diagnostic process

Segmentation with considerable shortcomings
I would not use the result in the diagnostic process

Segmentation with minor shortcomings.
I would use the result in the diagnostic process

Segmentation of very good quality.
I would use the result in the diagnostic process.

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The evaluation was based on a single criterion, i.e., the use of the result in the diagnostic process, as it was the applicability and added value in patient diagnostics that was the goal of the entire project. Due to the specific nature of the matter, the evaluations of respondents varied for respective segmentations. In a considerable number of cases there were always respondents who were willing to use a given segmentation, although the majority claimed otherwise. In-depth interviews with some of the respondents, carried out after the survey, revealed a high degree of subjectivity in the assessment, especially in marks 2 and 3. Many of them considered the same segmentation, seeing some deficiencies, to be good enough to be used in diagnostics, while their colleagues stated the opposite. Such subjective evaluation of studies is characteristic of imaging diagnostics, whose passage towards the objectivization of diagnoses is early days yet.

The acceptance criterion for a single segmentation, upon which we considered it to be correct, was that at least half of the respondents acknowledged that they would use it in the diagnostic process. This gave us an objective measure by which we could assess the progress and results of the project.The Mean Opinion Score method we have used and the way of its implementation have been positively evaluated during the CE certification audit and in the clinical validation we conducted.

Encountered problems and their solutions

From the large range of solutions developed during the R&D phase of the project we had to choose those that could be clinically proven and certified.

CONTEXT

After many months of research and development **we had worked out some solutions (algorithms)**, but we were not sure which we could “defend” clinically.

ACTION

Market research, consultations and in-depth workshops with doctors. Confronting what our product can offer with what is already available and what is missing in the end user’s (doctor’s) work. Choice of method for clinical validation

Choice of method for clinical validation

CONTEXT

The key element of our project was the segmentation of the change in the brain tissue caused by glioma, the most common brain tumor. The results of the work of the AI algorithm we applied, which involved deep learning, were images with a contour delineating the area identified by our model as the lesion we have been seeking. This area was then subjected to further analysis in the system, so its correct determination was crucial in order to obtain accurate results for the remaining analyses. The first, somewhat obvious idea for validation was to rely on ground-truth, specifically that part of it, which we had not used for network training. However, such a method has a fundamental downside. It allows us to evaluate the system's operation only on tests for which we have ground-truth, and its creation requires time and involvement of internal but also external specialists e.g., radiologists. We had been looking for a solution that would enable us to prepare segmentation for any research, and at the same time we would be able to assess its quality in an objective manner.

ACTION

This solution turned out to be a method borrowed from the telecommunications and marketing industry, called Mean Opinion Score. Its methodology is relatively simple. Respondents subjectively assess individual results and then their average is calculated. This average now constitutes an objective indicator, facilitating the validation of R&D project results, but not the only one.

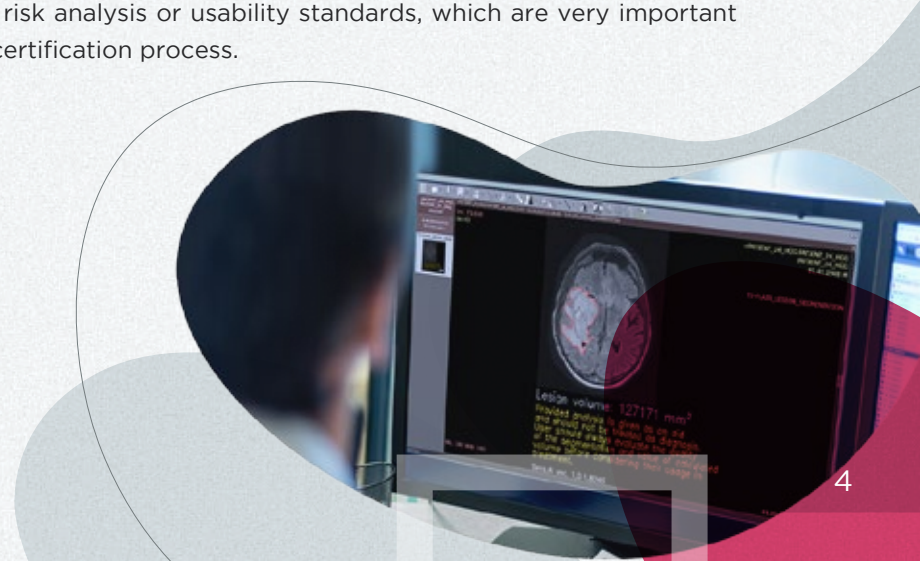
Documentation and risk analysis (All ISO standards)

CONTEXT

From the beginning of work on the product, documentation was kept. However, an in-depth analysis of the requirements in terms of certification only took place after obtaining results acceptable to business. At this point, it turned out that we had to make up for some shortcomings or deficiencies.

ACTION

The additional requirements provided by the business team are the time (cost) that we had to incur to go through further audits. After these experiences we drew conclusions and the documentation update was described in detail in our development processes. In addition, the delivery process also includes inputs and outputs for risk analysis or usability standards, which are very important during the certification process.



Good and bad practices

BAD PRACTICES

The documentation deficiencies that had to be addressed at the expense of stopping other work.

GOOD PRACTICES

Detailed description of the development processes (in relation to standard work in IT projects, in conjunction with ISO/IEC standards).

Notes from meetings – current and detailed records of the outcome of the meeting, which puts a lot of order in place, nothing “gets lost”.

Working closely with **Manager Responsible for Quality.**

Frequent communication, short but frequent updates – this allowed for quick reactions to emerging difficulties and did not allow for project downtime.

Flexible approach to Scrum methodology elements (shorter or more frequent sprints, task prioritization, flexible Daily Scrum or frequency of Retros.

Definition of Ready i Definition of Done aligned with the elements of ISO/IEC standards.

Checklists and ongoing, cyclical monitoring of progress.

Comala Workflows – a Confluence plug-in to manage the documentation, which in electronic form allows to archive the circulation, versioning and approval system of each element.

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About us

By developing advanced machine learning algorithms and AI quick - start modules **we create the possibility to automate and support the diagnostic process.**

At Graylight Imaging we believe that by combining a scientific approach, collaboration with medical experts and clinics around the world and high technological skills we are changing modern medicine.

So, if you have questions about our solutions - let's talk.

Get in touch

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