

PROACT 2.0

SERVICES DOCUMENTATION

[Revision: 08/07/2022]

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1. Introduction

1.1. Purpose

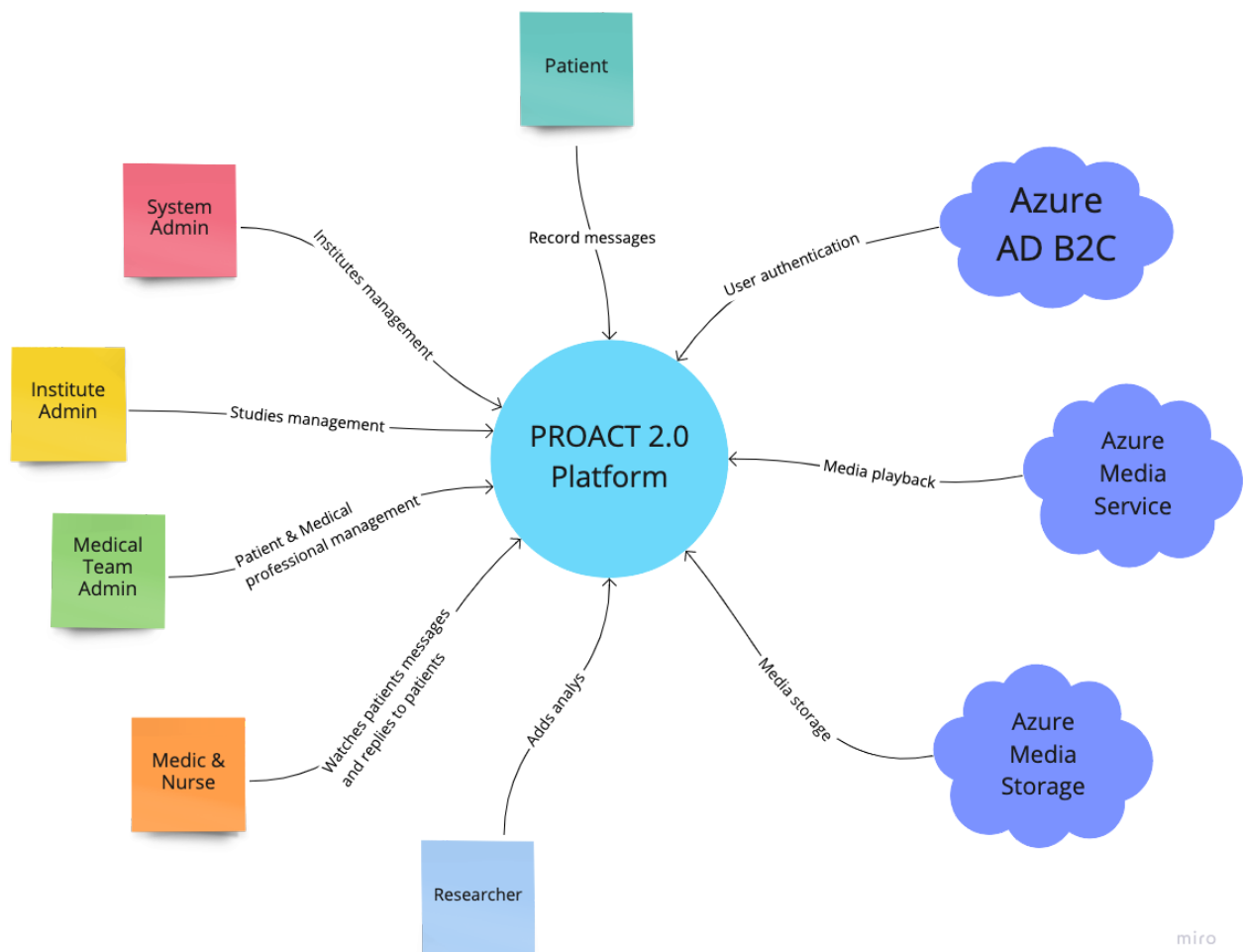
In developing a new medication, excellence in both clinical delivery and the understanding of the patient's tolerability are required to deliver optimal treatment. However, in early clinical studies it is difficult for patients to contribute directly to the understanding of a new compound. Patient Reported Opinions About Clinical Tolerability (PROACT 2.0) provides a new, simple and innovative way in which patients can collaborate.

Patients enrolled will be required to have their own mobile device and consent to taking part. Patients will use the PROACT 2.0 platform to upload video messages that will become instantly available to their clinical team. The team can reply to the patient directly from within the PROACT 2.0 platform. After a mandatory delay period, the patient's video is analysed and personally-identifiable information is removed. The information is then made available to the sponsor in an analytics module for manual classification using controlled vocabularies and subsequent export to a dedicated offline platform for further analysis and decision-making.

This document describes the technical aspects of the PROACT 2.0 platform, web portals, application programming interfaces and mobile applications.

2. System Strategy

2.1. System Context Diagram



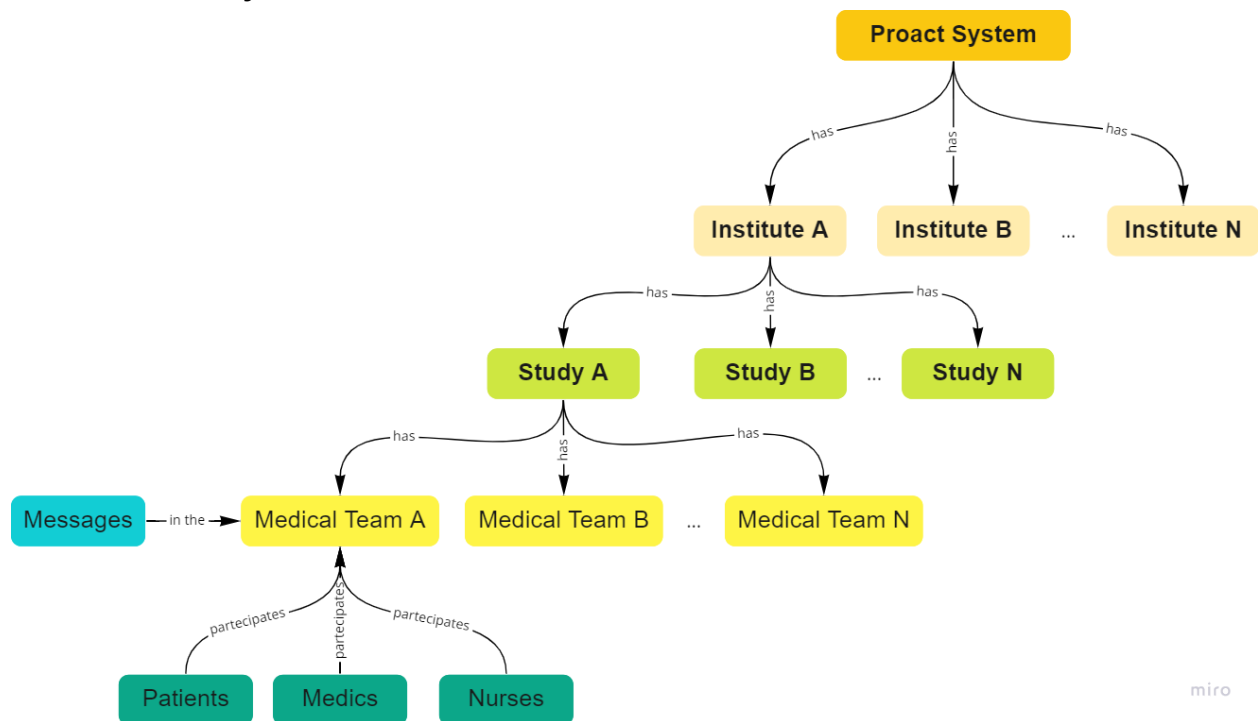
Context diagram description:

The PROACT 2.0 Platform clients are classified into two distinct groups: users and third-party systems. The users and their roles are described in **User Roles**.

The platform uses the following third-party system:

- **Azure AD B2C** to manage the identity of users.
- **Azure Media Services** for media encoding, storage and playback.
- **Azure Media Storage** to store the images uploaded by the user and video and audio that will not be encrypted for performance reasons.

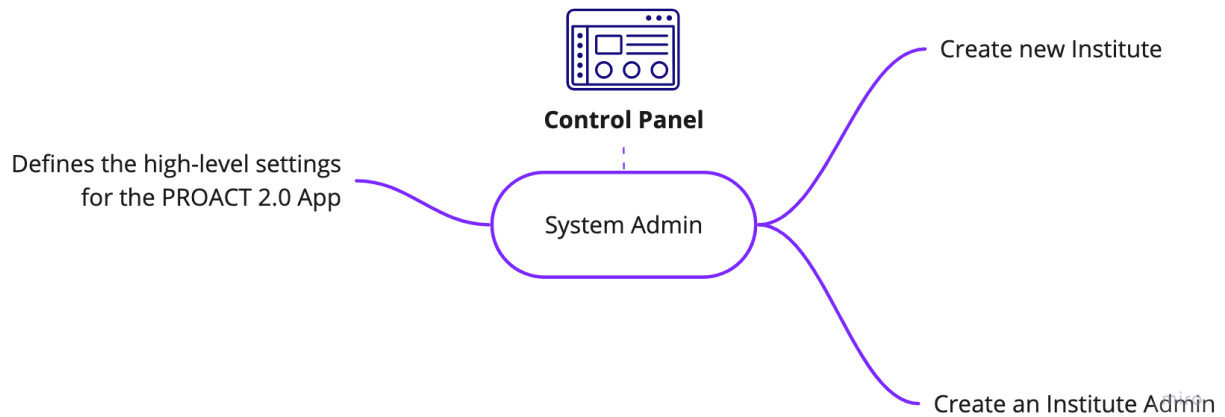
Context Hierarchy:



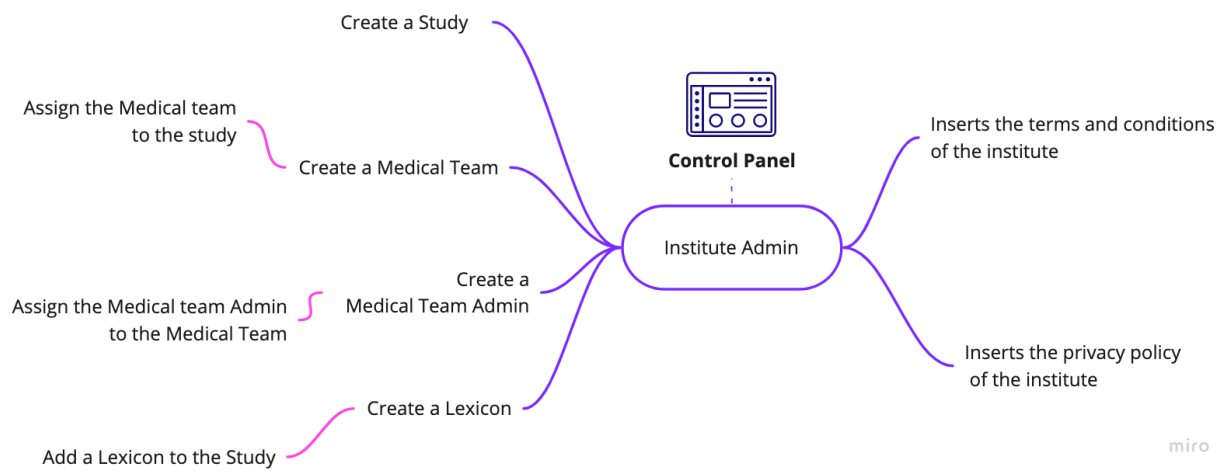
The PROACT System is the root, a System Administrator can create Institutes inside of PROACT, every Institute can have Studies, every study has Medical Teams and so on.

2.2. Users roles

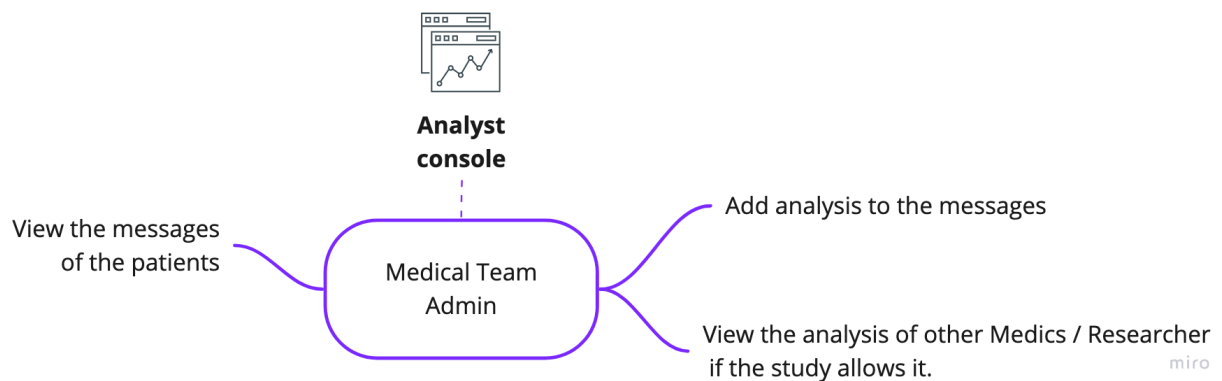
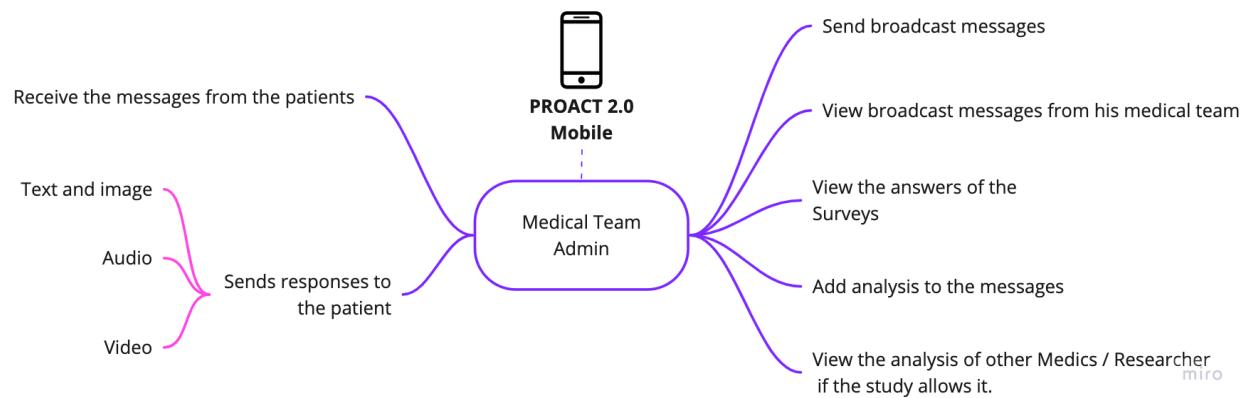
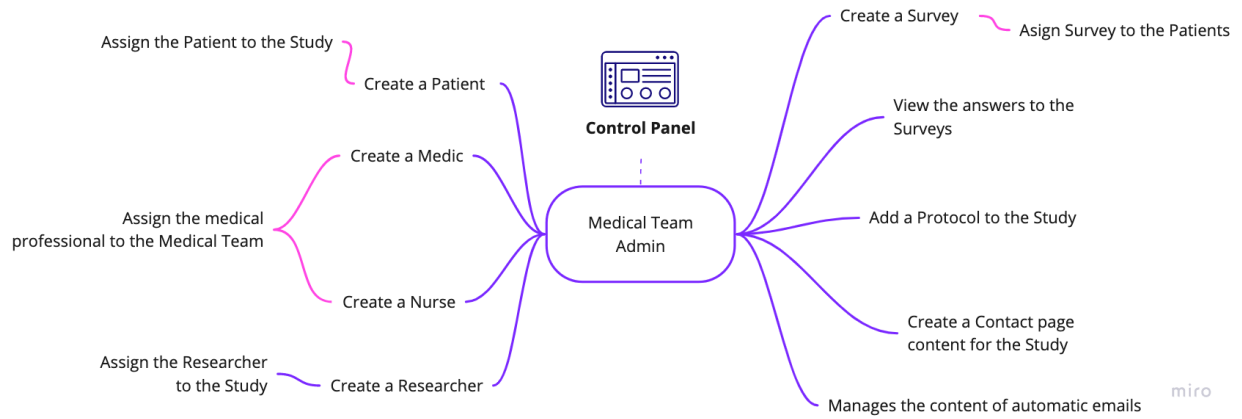
System Admin



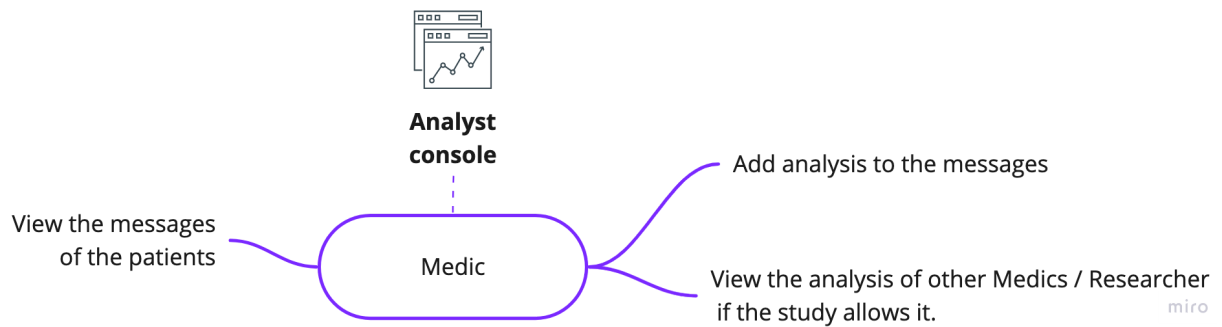
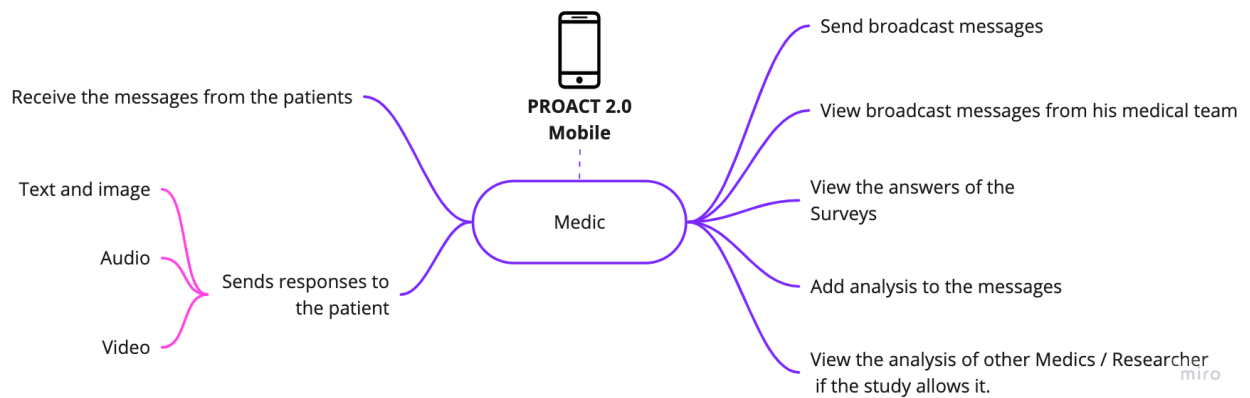
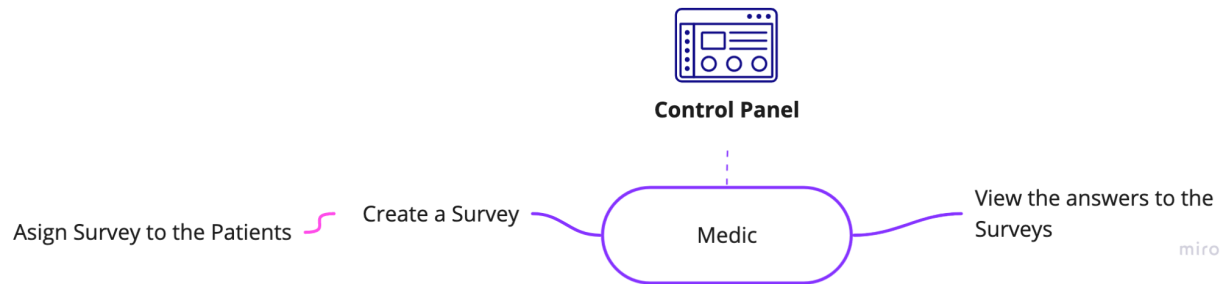
Institute Admin



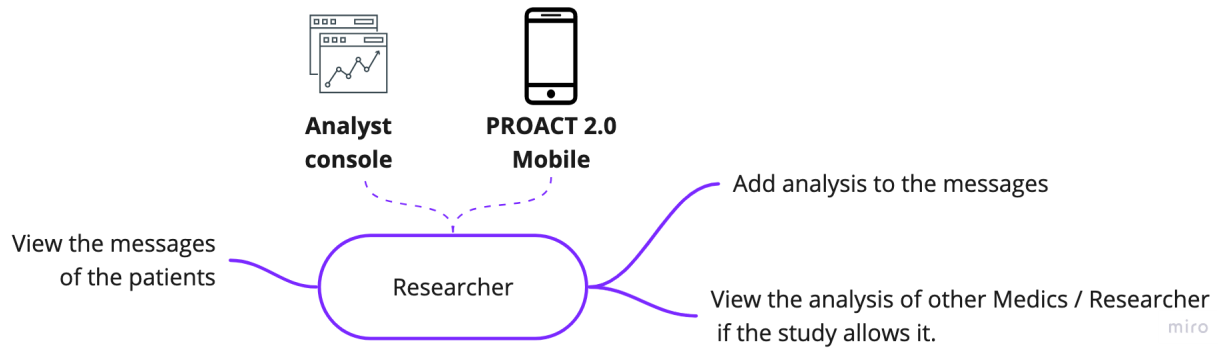
Medical Team Admin (MTA)



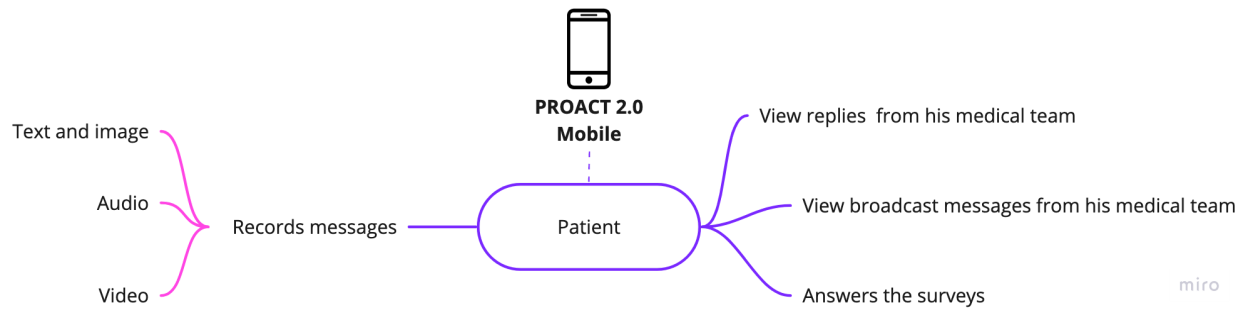
Medic



Researcher



Patient



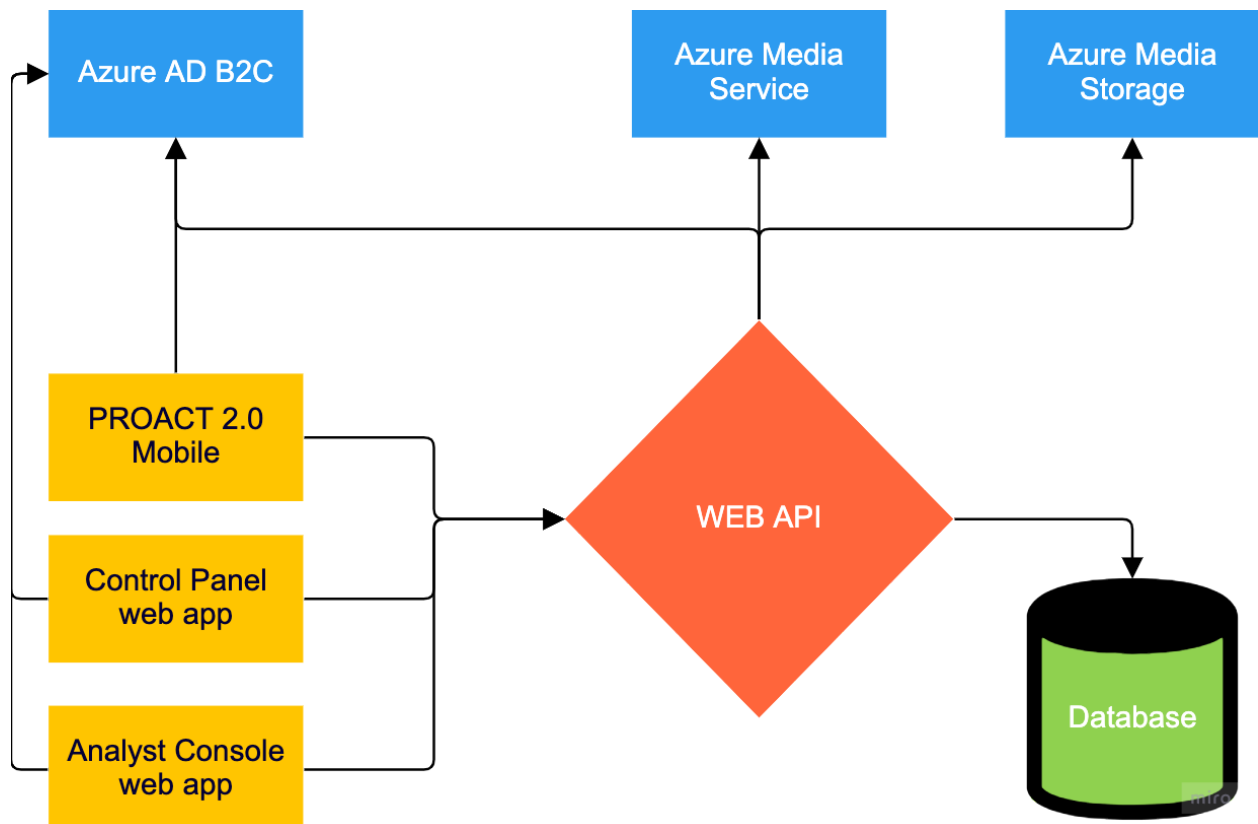
Channels (Access Method):

- **Mobile device access method:** Authorized Users will access the PROACT 2.0 system using their own mobile devices. User authentication will be managed by AzureAD, with OAuth 2.0 assurance.
- **Control Panel access method:** Medical Professionals and Administrators will be allowed to access the Web App using web browsers on their own devices. Azure AD will manage the authentication, with OAuth 2.0 assurance.
- **Analyst console access method:** Researchers and Medical Professionals will be allowed to access the Web App using web browsers on their own devices. Azure AD will manage the authentication, with OAuth 2.0 assurance.

Other Systems / Services:

- **Microsoft Azure Media Services** will be used to securely store media content and stream it to the authorized users

2.3. PROACT 2.0 Architecture Overview



PROACT 2.0 Architecture Overview

- **WebAPI:** Azure Api Management Service. Responsible for execution of business logic of the PROACT 2.0 System.
- **Database:** Azure SQL Database. Contains the user and message data.
- **Azure AD B2C :** responsible for user identity management and authentication using OAuth 2.0.
- **Azure Media Service:** stores audio/video messages and streams the content to authorized clients.
- **Azure Media Storage:** store the images uploaded by the users and the thumbnails created by AMS.
- **PROACT 2.0 Mobile:** allow the users to send and receive messages, and watch media files. The applications allow the user to perform a login.
- **Control Panel:** is the web application that allows authorized users to create new patients, medics and to manage the PROACT 2.0 System.
- **Analyst console:** Is the web application that allows authorized users to add analysis to messages.

3. Business Process Architecture Diagram

Authentication and authorization

The PROACT 2.0 system uses the OAuth 2.0 protocol for authorisation. For details about using OAuth 2.0. See Usage of OAuth 2.0 to Access the PROACT 2.0 API. An external identity service provider (Azure AD B2C) is used for user authentication. When a user successfully authenticates via Azure AD B2C, it sends a token with the user identity to the PROACT 2.0 application. The token contains user identity information (Azure AD B2C account id) and security data, such as token validity dates, electronic signature, application it was issued to etc.

Enrolling New Medical Professional

The process of medic enrolment is similar to the process of patient enrolment.

Enrolling New Patient

The PROACT 2.0 system will not store patient identifiable information other than those voluntarily contributed by the patient (e.g. in the form of the text/audio/video messages or profile pictures).

Enrolment process description

In order for the Team Admin to add a new Patient into the study, the TA needs to do the following:

1. The Team Admin accesses the PROACT 2.0 Admin Panel and initiates the correct study.
2. Team Admin executes the “Add Patient” function.
3. Team Admin enters a minimal set of patient’s info, such as e-mail and eCode. This data is not stored in PROACT 2.0, but is transferred to Azure AD B2C.
4. The PROACT 2.0 platform sends an account creation request to Azure AD B2C.
5. Azure AD B2C creates a new account and gives the PROACT 2.0 userID of the new account.
6. The PROACT 2.0 platform associates the Azure AD B2C UserId with the patient’s eCode and internal PROACT 2.0 account.

An Azure AD B2C account is created in a non-active state. To activate the new account, the patient has to use a one-time password sent to their e-mail and create a new permanent password. After that, the account can be used to access the PROACT 2.0 application.

Messages

Messages can be **Textual**, **Video**, **Audio** or an **Image**. Users can decide what kind of message they want to send. When a user wants to send a Video or Audio message, a “raw” message is created on the Server and so a media file is attached to it. Same thing when an Image is sent. If the user decides to send only a textual message, no attachment is required.

Create a new message

Patients can create new messages and Medics can reply to the patient messages. When a patient chooses to send a new message, this happens:

1. Patient opens the application and writes a new message, so the message is sent to the server.
2. The Server checks and saves the new message on the database.
3. The Server attaches the correct recipients to the message.
4. A result is sent back to the client.

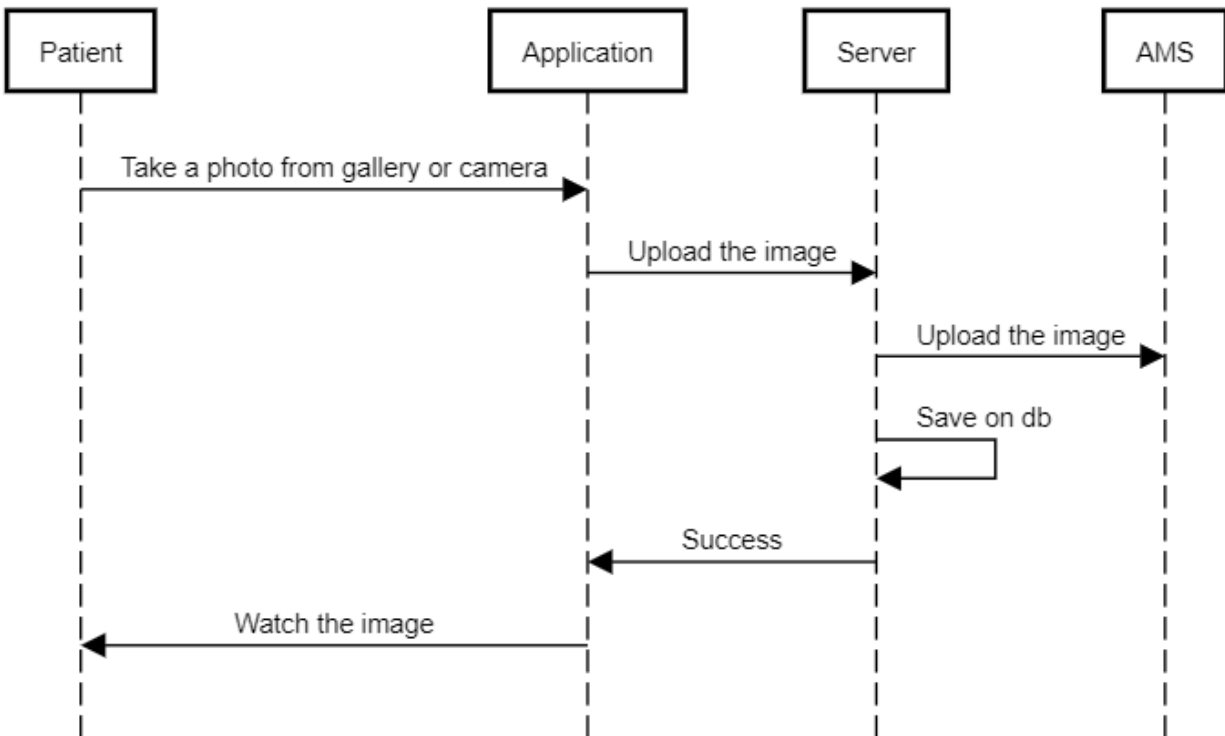
Create a new message with an Attachment:

When a user wants to create a new message with an attachment different things happen depending on the type of the attachment. The system uses Azure Media Service to upload the media files.

For the images:

1. The user creates a new message with text and uploads the image on the system.

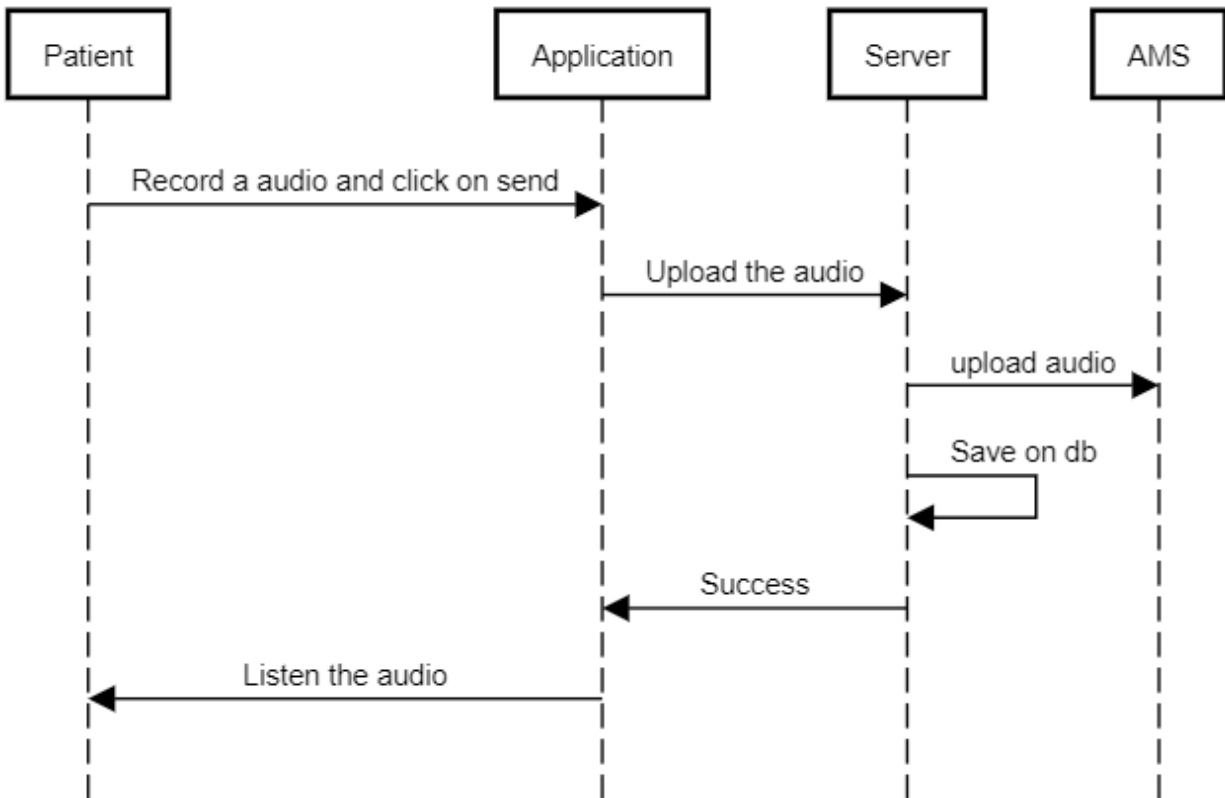
Image Attachment



For the audio:

1. The user records a new audio message.
2. The user awaits the upload operation.
3. The audio file is not encoded, but saved directly on Azure Media Service.

Audio Attachment



For the videos:

1. The user creates a new message and uploads the media file.
2. A success message is sent to the user.
3. The system encodes, creates a thumbnail and saves everything on Azure Media Services.
4. The user does not await the encoding time.
5. A notification arrives to the user when the media file is ready.

Video Attachment

