

# Speech enabled case reporting in your pocket!

## **IntelliCASE.**

The world's first mobile, customizable, ICSR solution  
with multi-language speech to text input.

# Speech enabled case reporting in your pocket!

**IntelliCASE** is the world's first mobile, customizable, ICSR solution that allows you to use speech to text in multiple languages.

**IntelliCASE** provides a simple, intuitive and easy way to complete a structured case report form on your mobile device. The Reporter indicates the fields required for a valid case, allows you to attach photos or other files, save the report as a draft if required and preview/edit it before submission to the Tracker and/or your Safety Database.

Case processing follow ups with urgency levels and required dates are also handled in-system direct to the user dashboard with email acknowledgements for each case/update submission.

**IntelliCASE** is E2B R3 compliant, fully validated to GAMP 5 GxP standards and recommendations, and all data handling and storage is GDPR compliant too.

Creating a case report, on the move, when you want, just became a whole lot easier.

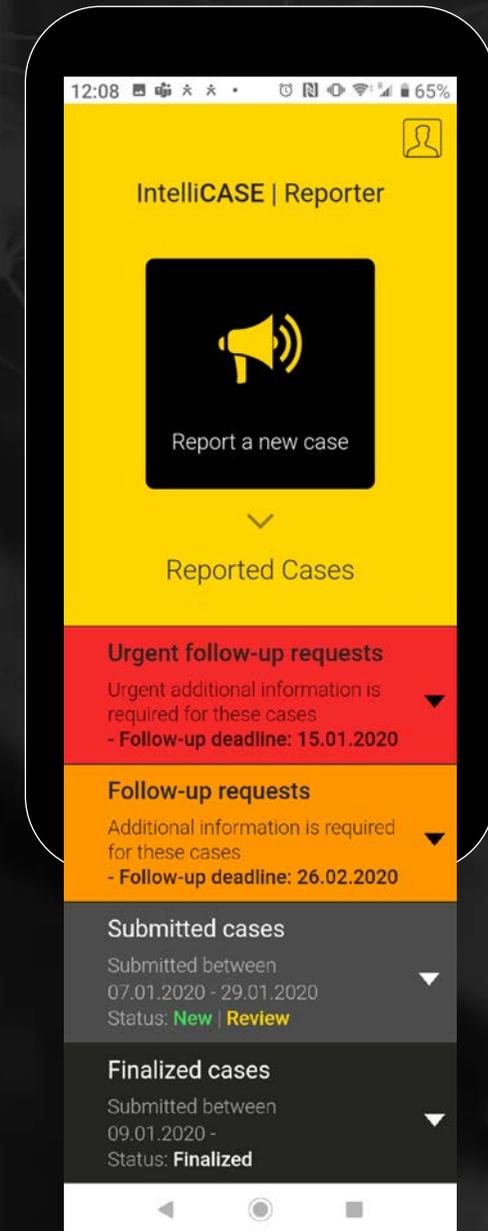
<https://www.arriello.com/automation/intellicase/>

## How fast is fast?

Our testing shows we can reduce the average processing time compared with a 'traditionally processed' case (reported by email, fax or call), **from 1.5 hours down to 30 minutes including QC check with IntelliCASE, a massive 66% time saving!**



# 66% faster...



# The IntelliCASE Tracker dashboard.

Filter by criteria.

Received date.

Essential identifiers.

User ID.

User administration.

The screenshot shows the IntelliCASE Tracker dashboard. At the top, there is a yellow header with the 'arriello' logo on the left, 'IntelliCASE | Tracker' in the center, and the user email 'intelicase.demo@arriello.com' along with links for 'Profile', 'Admin', and 'Sign out' on the right. Below the header, there are three buttons: 'Filter', 'Export Cases', and 'Users activity log'. The main content is a table with the following columns: 'Local Case ID', 'Received', 'Patient', 'Event(s)', 'Product(s)', 'Assignee', and 'Case Status'. The table contains 10 rows of case data. The fifth row is highlighted in yellow. At the bottom of the table, there is a pagination control showing page 1 of 6, and a dropdown menu set to 10 items per page.

Local Case ID	Received	Patient	Event(s)	Product(s)	Assignee	Case Status
<input type="checkbox"/>	19-02-2020 19:30	HS Female, 15 Years	Erythema nodosum	Cyclokinine	intelicase.demo@arriello.com	New
<input type="checkbox"/>	19-02-2020 19:20	WED Male, 5 Years	Gastroenteritis	Clindasine sodanite	intelicase.demo@arriello.com	New
<input type="checkbox"/>	19-02-2020 19:04	MC Female	Mal de crâne	Benefiprex	intelicase.demo@arriello.com	New
<input type="checkbox"/>	19-02-2020 18:54	DL Male, 40 Years	Visual colour distortions	Tramarotec	intelicase.demo@arriello.com	New
<input type="checkbox"/>	19-02-2020 18:47	FD Female, 29 Years	Eyelid haematoma Biliary neoplasm	Alitrexime	intelicase.demo@arriello.com	New
<input checked="" type="checkbox"/>	19-02-2020 18:37	GB Male	Nausea Headaches	Zentac	intelicase.demo@arriello.com	Finalized
<input type="checkbox"/>	19-02-2020 17:02	JD Male, 64	Hypersensitivity	Benazeriva	intelicase.demo@arriello.com	Review
<input type="checkbox"/>	19-02-2020 16:25	SD Male, 27	Nausea	Cortipitant	intelicase.demo@arriello.com	New
<input type="checkbox"/>	19-02-2020 15:38	GT Female, 24	Headache	Zentac	intelicase.demo@arriello.com	Follow-up
<input type="checkbox"/>	19-02-2020 14:28	HGW Female, 53 Years	nightmares Palpitations, + 1 more	Valentona	intelicase.demo@arriello.com	Review

Quick status indicator.

Export all or some cases.

Case/QC assignee.

Case Status identifier.

# Talk to the machine...

## Enter data by text, or speech, in your language.

But what makes **IntelliCASE** a unique world's first in the market is the ability to enter data from your voice, in over 100 languages, alongside keyboard text entry. That makes the entry of more detailed or longer information easier, and the likelihood of better and more detailed data higher.

And the system can be programmed to learn and recognize 100 specific product/treatment/condition keywords for each question.

Using a clear, intuitive and easy to use interface with voice capabilities frees users up from having to report cases by email and traditional forms, and encourages **faster, better, smarter** reporting overall, with downstream effort reductions and reduced follow ups.

The user interfaces for both the Reporter and Tracker modules can be customized to your language requirements beyond English.

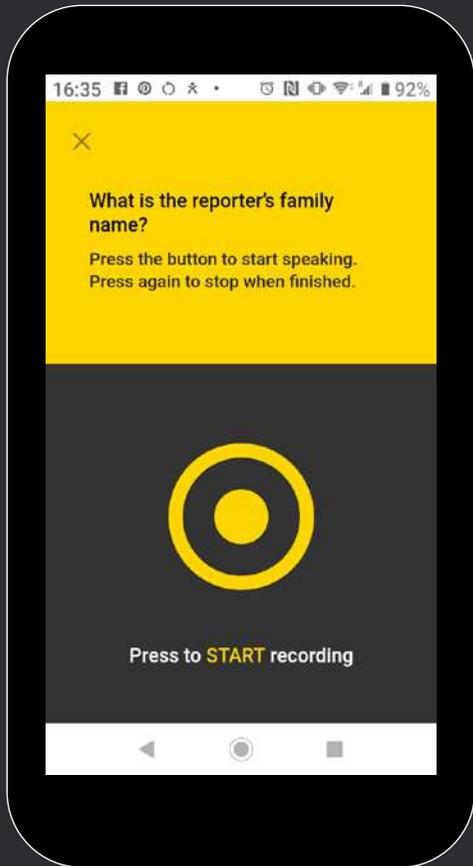


**You can use speech to text input wherever the Mic icon is next to a field using the same fast and easy 5-step process every time.**

# 1.

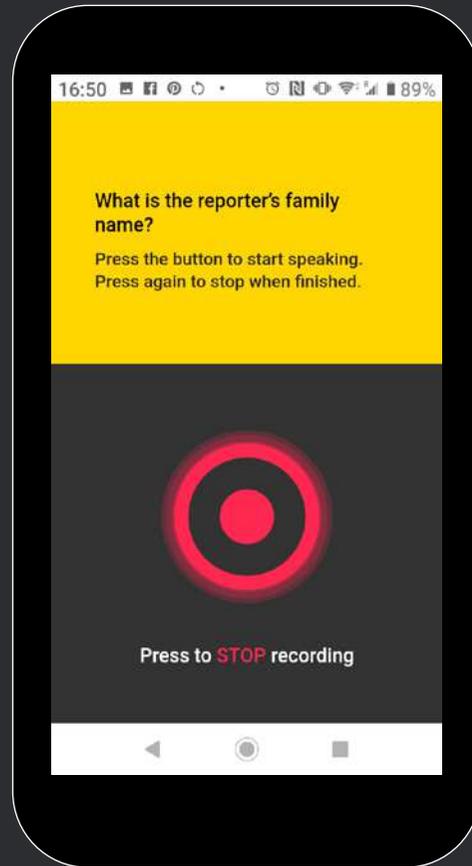
**Tap the Mic icon to enter text by speech...**

# 2.



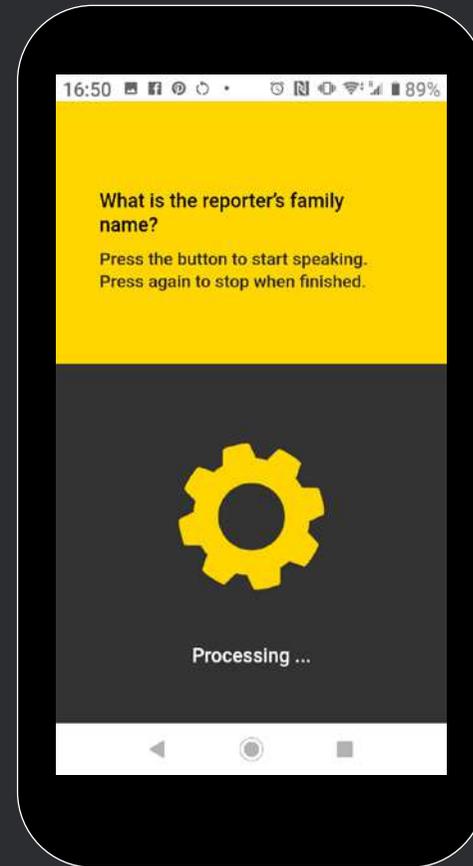
...hit the button to record your voice entry...

# 3.



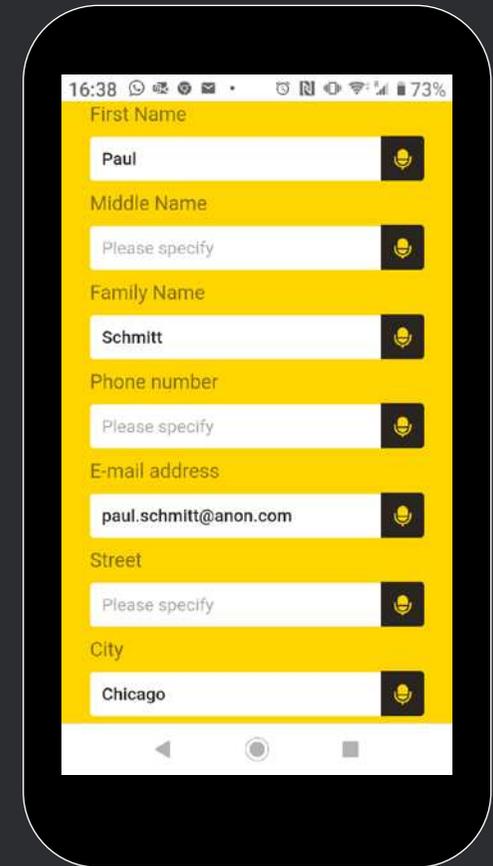
...hit the button again to stop recording...

# 4.



...the system then processes your speech...

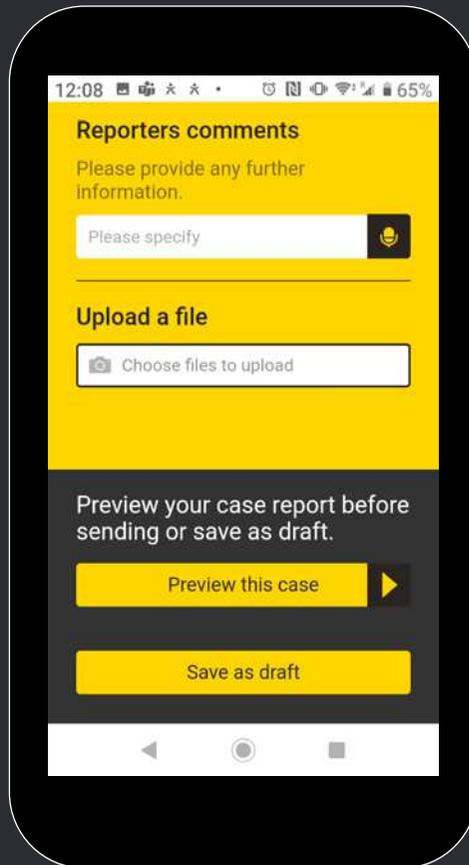
# 5.



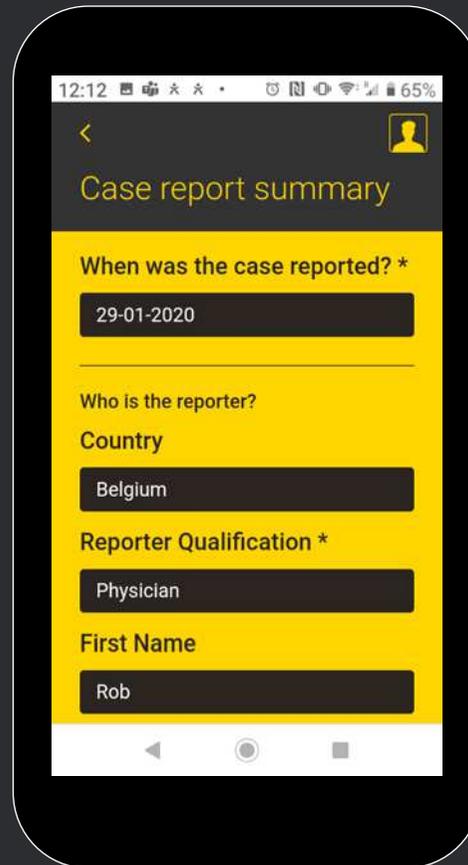
...and simply enters your speech as text!

# You're in control...

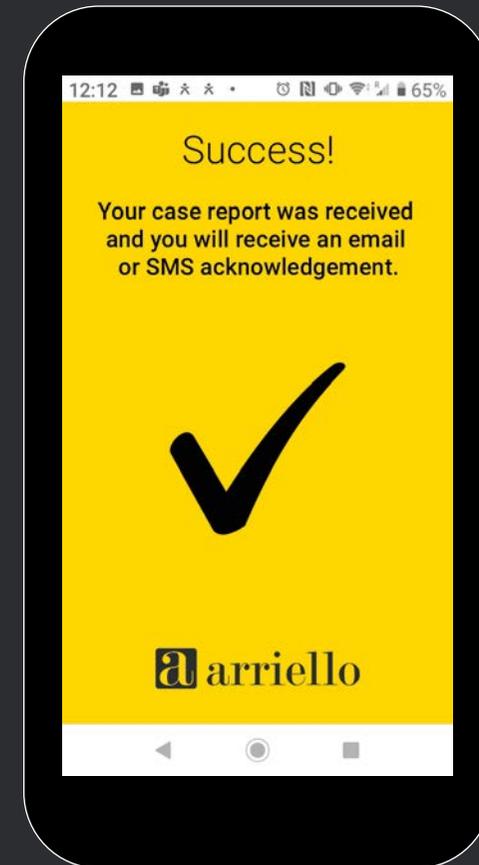
Preview and edit, save as a draft, re-edit, submit...you're in control of your reporting.



Add files directly from your device, preview the case or save as a draft.



Your entries are shown in the preview and you can edit them or submit the case.



Submit the case and receive a visual confirmation, an email acknowledgement, and a Reporter dashboard update.

# Easy structured data input...

IntelliCASE uses multiple ways to structure case information for processing.

17:44 65%

What information do you have about the patient?

Initials  
Please specify

Birthdate

Onset Age Onset Age Unit  
Please choo...  
Please choose Days  
Please choose Weeks  
Please choose Months  
Please choose Years  
Gestation Period Gestation Period Unit  
Please choo...

Drop downs are used for even faster entry of fixed field responses.

11:53 68%

Questions marked **like this \*** are required to create a 'valid' case. An Arriello PV specialist will contact you if these questions do not have information.

When was the case reported? \*  
Report date is required.

Who is the reporter?  
Country  
United States

Reporter Qualification \*  
Reporter qualification is required

The fields required for a 'valid' case are highlighted in red.

12:07 65%

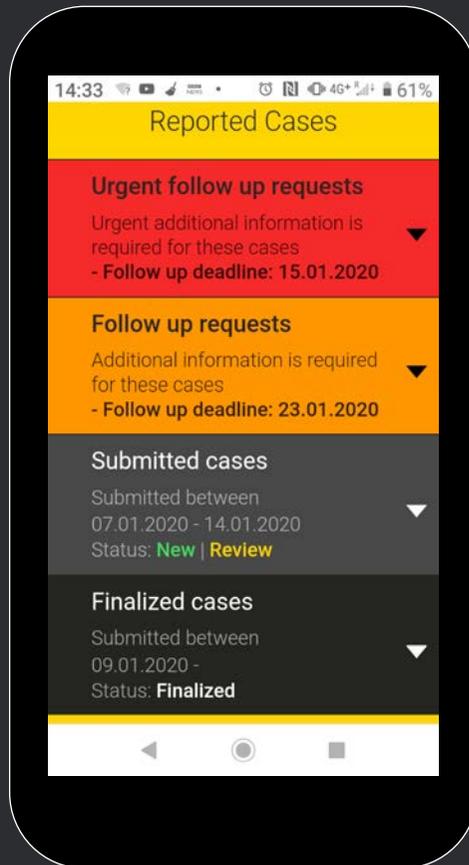
Association(s) \*  
Association(s) between Drug and Event \*  
1. Please choose  
Causality Assessment by reporter  
Please specify  
+ Add Association  
+ Add Product

Reporters comments  
Please provide any further information.  
Please specify

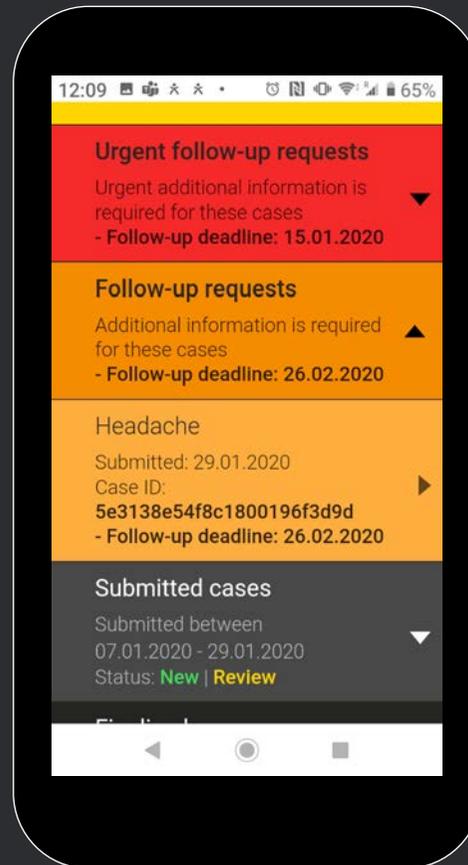
Multiple events, products and event/product associations can be created as needed.

# In system follow-ups...

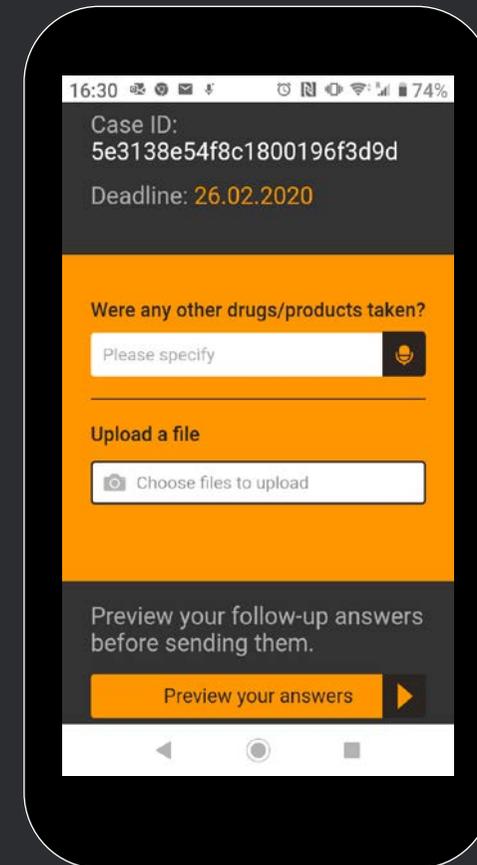
Easy case viewing and in system follow-ups with urgency levels direct to your dashboard for streamlined case processing.



The dashboard shows your cases and any non/urgent follow-up requests and responses.



Expand the follow-ups section by pressing the arrow to reveal each request.



Submit a response just like a case report by text/speech input before preview/submission.

# Tracker features.

## In-system follow-ups.

PV specialists can create a follow-up question which is sent directly to the Reporter dashboard with an urgency level automatically generated and updated from the due date of the request.

The screenshot shows the 'Add Follow-up' form. At the top, there is a dropdown menu for 'Association(s) between Drug and Event' with 'Headache' selected. Below it are fields for 'Case ID' and 'Reporter ID'. A section titled 'Reporters comments' has a text input field. The 'Follow-ups' section contains a question 'Were any other drugs/products taken?' with a text input field, a 'Due date' field set to '24/02/2020', and a 'Reporter name' field with 'Reporter name (p. 01/2020)'. A green button labeled 'Save' is at the bottom right.

## Instant translation.

IntelliCASE Tracker provides an instant quick translation feature that allows PV specialists to make an initial quick assessment of a case ahead of a request for a certified translation.

The screenshot shows the 'Case detail' page. At the top, there is a navigation bar with the 'arriello' logo and 'IntelliCASE | Tracker'. A dropdown menu for 'Language' is open, showing options: English (UK), English (USA), French, Spanish, and Greek. The 'Case' section includes fields for 'Case ID', 'Local Case ID', 'Report date by Author', 'Report date by Reporter', and 'Day ID'. The 'Who is the reporter?' section includes fields for 'Country', 'Qualification', 'First Name', 'Middle Name', and 'Family Name'.

## Edit event, product and association information.

You can edit information concerning events, product/s and event/product associations in the case details. When a case is saved after editing a new version number is created for a full audit trail.

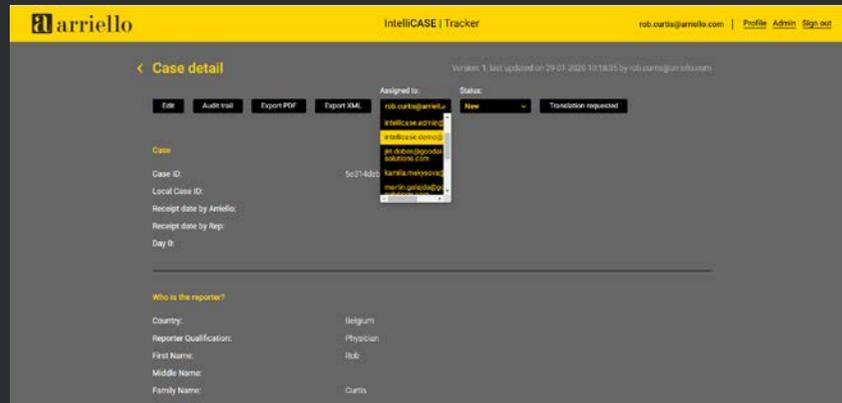
The screenshot shows the 'Product' form. It includes fields for 'Product name', 'Product characterization', 'Active substance(s)', 'Dosage amount', 'Dosage frequency', 'Start Date', 'End Date', 'Action taken with product', 'Batch number', 'Product Therapeutic Indication', and 'Association(s) between Drug and Event'. The 'Association(s) between Drug and Event' dropdown is set to 'Erythema nodosum'. A green button labeled 'Save' is at the bottom right.

An instant translation is offered for any non-recognized text in a field.

The screenshot shows the 'Event' form. It includes fields for 'Patient Age Group', 'Patient Sex', 'Gestation Period', 'Gestation Period Unit', 'Address Event or Source Information', 'Start Date', 'End Date', 'Duration', and 'Outcome'. A 'Translate' button is next to the 'Address Event or Source Information' field. Below the form, there are sections for 'Results in Death', 'Life Threatening', 'Hospitalization', and 'Disabling', each with radio button options for 'Yes', 'No', and 'No Information'.

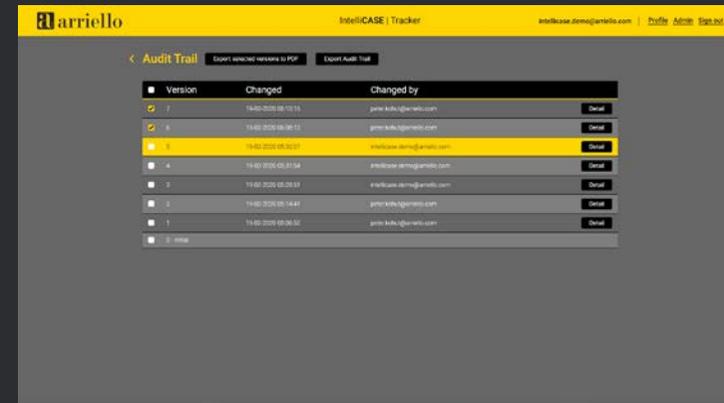
### Case detail.

Assign or re-assign a case directly from the case overview screen.

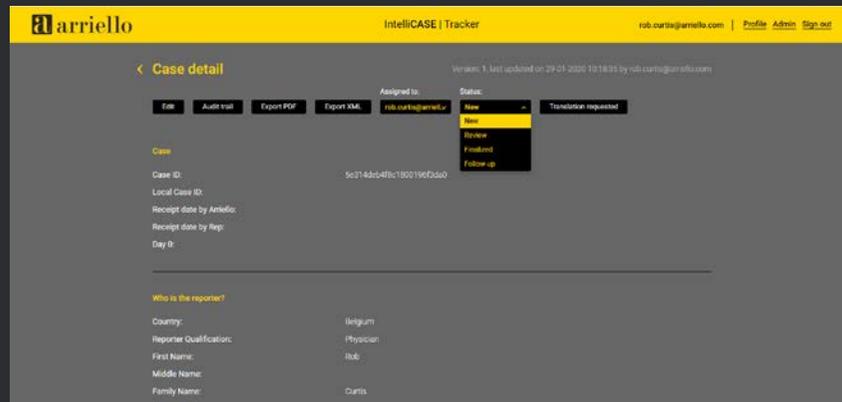


### Full Audit Trail.

With IntelliCASE Tracker can view and export an audit trail for the entire history of a case or selected versions, the choice is yours.



Set the status of a case directly from the case overview screen.



### From intelligent automation to artificial intelligence.

The IntelliCASE system was built in partnership with Artificial Intelligence specialists Good AI with an expectation that at some point we would be able to extend the use of your case report data if required.

Depending on the amount of data you have, and what you might want to know (or what you didn't think of until now), we can create a further tailored custom solution using algorithmic and machine learning capabilities that can provide impactful business insights or predictors.



# IntelliCASE features and benefits summary.

## **E2B compliant.**

Connects to your E2B R3 safety database and can be adapted for E2B R2.

## **Validated.**

GAMP 5 GxP validated for auditing and quality management compliance.

## **In-system follow-ups.**

Urgency levels and dates direct to the user dashboard.

## **Multi-lingual.**

Selection of multiple voice input languages.

## **Customizable.**

Your language interface/system/user requirements.

## **Accessible.**

Outputs data/audit trails to most common formats, customizable to any others.

## **AI capable.**

Developed to use custom insight algorithms with your data.

## **Easy.**

Clear, intuitive and easy to use interface.

## **Portable.**

When and where you want online.

## **Voice or text input.**

It's your choice.

## **Fast.**

Direct transfer to Tracker and client safety DB.

## **Efficient.**

Faster, easier input, better data, rapid/reduced follow ups, instant acknowledgements.

## **Expert design.**

Developed by PV people, for PV people.

## **Focused.**

PV specialists spend more time on thinking and analysis than labor intensive administration = more focus on safety.

<https://www.arriello.com/automation/intellicase/>

**from development to market.  
faster. better. smarter.**



## **About us.**

Arriello has been a leading provider of risk management and compliance services to the Life Sciences sector since 2008.

These include Market Consultancy, Global Regulatory Affairs strategy and implementation, Full and Local Pharmacovigilance solutions, Clinical Drug Safety, and Quality and Compliance auditing and systems.

Our brief is simple; to make the process from development to market faster, better and smarter.

Headquartered in Ireland, with European operations in Central Europe, we provide expert Market Access guidance across the EU, US, LATAM, CIS, MENA, Asia and South Africa.

With our extensive global vendor network, ISO 9001 certification, years of experience and satisfied clients, including Global Originators, Biotech, Generics and CROs, you can be confident in our ability to deliver.

However complex or simple your requirements, you can rely on us as a trusted partner.

### **Global Headquarters**

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