



FAQs

MERLIN.NET™ PATIENT CARE NETWORK (PCN)
EUROPEAN CLOUD PLATFORM
LIMITED MARKET RELEASE (LMR)

MERLIN.NET™ PATIENT CARE NETWORK (PCN) EUROPEAN CLOUD PLATFORM

We are here to help if you have questions or concerns and are committed to providing you with the necessary support every step of the way!

FREQUENTLY ASKED QUESTIONS (FAQS)

Why is a new Merlin.net PCN European cloud platform being rolled out?

Abbott is committed to providing innovative and secure solutions for remote monitoring of patients worldwide.

The migration to European cloud-based infrastructure addresses the preference of many EU, European Economic Area (EEA), and UK customers to see their patient data hosted in the EU rather than the U.S. The new Merlin.net PCN European cloud platform leverages the Microsoft Azure industry-leading, state-of-the-art cloud data storage solution.

How will this rollout take place?

Abbott is committed to developing products that meet the highest standards for quality and reliability. Abbott undergoes a thorough product lifecycle process from Research & Development to the global commercialization of life-changing technologies. Part of the process includes, but is not limited to, market research, investigative trials, formative user testing, customer reviews, and limited market releases.

The Merlin.net PCN European cloud platform will be rolled out as part of a gradual series of Limited Market Releases (LMR). These LMR phases allow a select group of customers to experience a product for the first time before it is broadly introduced to the market. The LMR allows users to provide feedback for our Product Development teams to make final adjustments as necessary before launching the product into what we call the Full Market Release (FMR). For software products such as Merlin.net PCN, an LMR provides a means of ensuring that the system works smoothly in a “real-world” environment, allows fine-tuning of the application, and optimizes product performance before a FMR.

The rollout will be completed in four LMR phases:

- 1. LMR1** is for new patient enrollments only. Device enrollment is limited to radio frequency and inductive devices that use Merlin@home™ (excluding Bluetooth® or conductive devices) (**see device list**). Some existing Merlin.net PCN features will be unavailable during this phase (**see feature list**), and there will be no transfer of existing patient data from the legacy Merlin.net PCN to the new European cloud platform. Participating clinics will have two Merlin.net PCN accounts in this phase of the LMR (existing legacy account and new European cloud platform account).

- 2. LMR2** is also for new patient enrollments only, but adds the ability to enroll Gallant™, Entrant™, and Neutrino™ ICD and CRT-D devices. Again, some existing Merlin.net™ PCN features will be unavailable during this phase (**see feature list**), and there will be no transfer of existing patient data from Merlin.net PCN. Participating clinics will have two Merlin.net PCN accounts in this phase of the LMR (existing legacy account and new European cloud platform account).
- 3. LMR3** includes data migration for radio frequency and inductive pacemakers, ICD, and CRT-D devices that use Merlin@home™ transmitters for remote monitoring, as well as Gallant, Entrant, and Neutrino ICD and CRT-D devices (i.e., that use myMerlinPulse™ Mobile App) to the new European cloud platform. The Merlin.net PCN features that were unavailable in LMR1 and LMR2 will be reinstated at this time.
- 4. LMR4** adds Abbott insertable cardiac monitor (ICM) devices and data migration for ICM devices to the new European cloud platform. Additionally, SyncUP™ support will be enabled. There will be a full market release to all patients (new and existing, for all products) in the EU, EEA, UK, and Switzerland after LMR4 is complete.

When will my existing patients be migrated?

Merlin.net PCN European cloud platform will be rolled out as part of a gradual series of LMRs. The migration of existing patient data will start in LMR3 and will be completed in LMR4:

- 1. LMR1** is for new patient enrollments only. Device enrollment is limited to radio frequency and inductive devices that use Merlin@home (excluding Bluetooth® or conductive devices). **No existing patients are migrated during LMR1.**

This means that for new patient enrollments of other devices and existing patients, the original U.S.-based Merlin.net PCN portal remains available to offer the service of remote monitoring. For this reason, you will have two Merlin.net PCN accounts in this LMR (existing account and new European cloud platform account).

- 2. LMR2** adds the ability to enroll Gallant, Entrant, and Neutrino ICD and CRT-D devices, and is only for new patient enrollments. **Again, no existing patients are migrated during LMR2.**

The existing patients and other devices remain on the original U.S.-based Merlin.net PCN portal. For this reason, participating clinics will have two Merlin.net PCN accounts in this phase of the LMR (existing account and new European cloud platform account).

- 3. LMR3** will include data migration for radio frequency and inductive pacemakers and ICD and CRT-D devices that use Merlin@home transmitters for remote monitoring as well as Bluetooth® Gallant, Entrant, and Neutrino ICD and CRT-D devices using myMerlinPulse Mobile App to the new European cloud platform. This means **your existing patients for these devices will be migrated from the original U.S.-based Merlin.net PCN to the new European cloud platform.**

However, the new patient enrollments and existing patients using ICM devices remain supported on the legacy U.S.-based Merlin.net™ PCN portal.

4. LMR4 adds Abbott ICM devices and data migration for ICM devices to the new European cloud platform. Also, SyncUP™ support will be enabled. From LMR4, **all your existing patients will be migrated to the new European cloud platform for Merlin.net PCN.** In addition, all your new patient enrollments can be completed on the new solution, too.

As part of each LMR, your local representative will stay in close contact with you to answer all your questions and initiate proactive communication. This means that your representative will reach out to you at different stages to keep you informed of key activities and, most importantly, of the exact dates when your clinic and patients will be included in the upcoming LMR.

What is a Limited Market Release (LMR)?

The LMR allows a select group of customers to experience a product for the first time before it is broadly introduced to the market. The LMR allows users to provide feedback for our Product Development teams to make final adjustments as necessary before launching the product into what we call the Full Market Release (FMR). For software products such as Merlin.net PCN, a limited market release provides a means of ensuring the system works smoothly in a “real-world” environment, fine-tuning the application, and ensuring product performance is optimized before a full market release.

We believe the decision to launch products using an LMR process helps us focus on providing the best possible product and service to all our customers. We aim to provide a seamless and efficient product experience that meets your clinic needs.

What is changing?

With the Merlin.net PCN European cloud platform, we are enhancing the overall user experience, so you can access the information you need efficiently. In addition to this, we are making some minor cosmetic changes to our platform, giving it a more modern and streamlined look and feel. These changes should not affect your workflow.

We are also moving data storage from our U.S.-based data servers to a regionalized European cloud platform. We are taking all the steps to ensure this transition is seamless and that your data continues to remain safe, secure, and in compliance with current data privacy policies and regulations.

Is my patient's data safe?

Yes. The move to a European cloud platform for Merlin.net PCN was designed to comply with data privacy regulations while continuing to keep patient data safe and secure on the Microsoft Azure system.

How do I contact Remote Care Technical Support?

You may contact your local Abbott Representative or Remote Care Technical Support via email or phone if available in your country:

Austria:	crmtechnischersupport@abbott.com	+43 1891 222 81
Belgium:	merlinsupportbenelux@abbott.com	+32 800 122 33
Finland:	remote.monitoring@abbott.com	+46 8 474 4756
France:	telecardiologie@abbott.com	+33 0 800 000 565
Germany:	crmtechnischersupport@abbott.com	+49 6196 77 11 444
Ireland:	ukiemerlin@abbott.com	+353 1 800 719 893
Italy:	supportomerlin@abbott.com	+39 02 35961070
Luxembourg:	merlinsupportbenelux@abbott.com	+32 800 122 33
Netherlands:	merlinsupportbenelux@abbott.com	+31 800 020 17 29
Norway:	remote.monitoring@abbott.com	+46 8 474 4756
Poland:	remote.monitoring@abbott.com	+46 8 474 4756
Spain:	soporte.merlin@abbott.com	+34 900 94 32 39
Sweden:	remote.monitoring@abbott.com	+46 8 474 4756
United Kingdom:	ukiemerlin@abbott.com	+44 800 389 2714

Does this rollout impact both the Merlin.net PCN Arrhythmia (EP) and Heart Failure (HF) portals?

During the LMR, it will be necessary for users to log in separately to the Merlin.net HF portal to access data currently available in that system, as there will not be an option to directly access the HF portal from the Merlin.net PCN European cloud platform.

Please consult your local Abbott HF representative for more information regarding the new HF portal.

Will this change interrupt the service of remote monitoring?

No. The service of remote monitoring will not be interrupted because of the rollout. While different devices will be included in different LMR phases, the service of remote monitoring will continue to serve uninterrupted. The rollout will be completed in four LMR phases. For more details on the rollout and/or migration of existing patients, please consult the respective questions, “**How will this rollout take place?**” and, “**When will my existing patients be migrated?**”.

When will I be notified of the upcoming change effectivity date?

We are committed to providing you with the necessary support every step of the way. We have designed an informational webpage, [Cardiovascular.Abbott/MerlinCloudEU](https://www.abbott.com/merlincloud), to communicate all future notifications and updates. Please bookmark this website and check back frequently for updates.

Why must I use two portals to support my patients?

As part of the LMR process, we gradually roll out the new Merlin.net PCN cloud data storage solution. The LMR allows a select group of customers to experience a product for the first time before it is broadly introduced to the market. This allows users to provide feedback for our Product Development teams to

make final adjustments as necessary before launching the product into what we call the FMR. This approach provides a means of ensuring that the system works smoothly in a “real-world” environment, fine-tuning the application, and ensuring that product performance is optimized before a full market release.

However, to ensure that service of remote monitoring continues uninterrupted, the original U.S.-based Merlin.net™ PCN portal will continue to operate parallel to the new European cloud platform. This situation will apply until all existing patients are migrated to the new Merlin.net PCN European cloud platform.

We understand that managing multiple accounts could be confusing and take some extra time, so we have taken steps to ensure a smooth onboarding process.

For more details on the migration of existing patients, please consult the question, **“When will my existing patients be migrated?”**.

Where are my existing patients? How do I manage my existing patients now?

Rest assured that your existing patient data will not be moving to the European cloud platform with LMR1. You can still access their data with the U.S.-based data server version of Merlin.net PCN. For this reason, there will be two portals you will need to access to support your patients. For more details, please consult the question, **“Why must I use two portals to support my patients?”**.

For the other LMR phases, please consult the question, **“When will my existing patients be migrated?”**.

Can I transfer patients between the European cloud platform and the U.S.-based data version of Merlin.net PCN during the LMR phases?

No. Once patients are enrolled in the new European cloud platform account portal, patient data will need to remain in the same portal. If new patients are enrolled in the original U.S.-based Merlin.net PCN portal, they will be migrated as part of the LMR rollout plan. For more details, please consult the question, **“When will my existing patients be migrated?”**.

Is SyncUP™ Remote Monitoring Support as a service supported in the Merlin.net PCN European cloud platform?

While SyncUP as a service will eventually be offered in the European cloud platform, this will not be available at the start of the LMR.* For more details regarding LMR phases, please consult the question, **“How will this rollout take place?”**. Clinics that use SyncUP as a service will be invited to participate in a later phase once this service is supported in the European cloud platform.

***This applies for all countries except for France. In France, SyncUp as a service will continue to operate from LMR1.**

Why am I not able to access existing patient data in the Merlin.net™ PCN European cloud platform?

The Merlin.net PCN European cloud platform will be rolled out as part of a gradual series of LMRs. This means your existing patients will also become gradually available in the new European cloud platform. Until the day of this migration, you are still able to access existing patient data in the original U.S.-based Merlin.net PCN Portal.

For the exact details of when your existing patients will become available in the European cloud platform, please consult the question, **“When will my existing patients be migrated?”**.

Can I enroll patients on both platforms during the LMR?

The Merlin.net PCN European cloud platform will be rolled out as part of a gradual series of LMRs. This means that as the LMR phases progress, you will be able to enroll more types of devices on the new European cloud platform. Likewise, it will still be possible to enroll new patients on the original U.S.-based Merlin.net PCN. Only when all existing patients will be migrated to the cloud platform, will this no longer be possible on the U.S.-based platform. For more details regarding the content of the LMR phases, please consult the question, **“How will this rollout take place?”**.

How long will the LMR phases last?

The Merlin.net PCN European cloud platform will be rolled out as part of a gradual series of LMRs. This means that the migration of existing patients will also be completed in phases. Upon completion of LMR4, all Merlin.net data for devices used in the EEA, UK, and Switzerland will be stored in the EU.

How will LMR2 impact myMerlinPulse™ Mobile Application (App) on the patient’s mobile device?

During LMR2, only new patients will be enrolled on the Merlin.net PCN European cloud platform. These patients can download the most recent version of the myMerlinPulse Mobile App on their devices.

Abbott will release an update to the myMerlinPulse Mobile App, accessible through a public mobile application store, before LMR2. This version will support the new Merlin.net PCN European cloud platform and the original U.S.-based Merlin.net PCN Portal.

Do current patients using Gallant™, Entrant™, and Neutrino™ ICD and CRT-D devices need to be concerned about the upgrade to the myMerlinPulse Mobile App for LMR2?

No, existing patients using Gallant, Entrant, and Neutrino ICD and CRT-D devices will not be affected by the upgrade of the myMerlinPulse Mobile App for LMR2.

Only new patients will be enrolled on the Merlin.net PCN European cloud platform during LMR2. Existing patients can continue using their current version of the myMerlinPulse Mobile App, and the original U.S.-based Merlin.net PCN portal will continue supporting the existing Merlin.net NGQ Pulse app version.

Do existing Gallant, Entrant, and Neutrino ICD and CRT-D device patients need to upgrade their myMerlinPulse Mobile App?

Abbott recommends that patients always update their myMerlinPulse Mobile App with the newest version, accessible through a public mobile application store. However, the original U.S.-based Merlin.net PCN portal will keep supporting all existing versions of the myMerlinPulse Mobile App.

Which devices will be supported in each LMR Phase?

A device reference list is provided for your convenience.

Device Name	Implementation Phase
Accent™ Pacemaker	Phase I
Allure™ CRT-P	Phase I
Allure Quadra™ CRT-P	Phase I
AnalyST™ ICD	Phase I
AnalyST Accel™ ICD	Phase I
Anthem™ Pacemaker	Phase I
Assurity™ Pacemaker	Phase I
Assurity MRI™ Pacemaker	Phase I
Atlas™ ICD	Phase I
Convert™ ICD	Phase I
Current™ ICD	Phase I
Current Accel™ ICD	Phase I
Ellipse™ ICD	Phase I
Endurity™ Pacemaker	Phase I
Endurity MRI™ Pacemaker	Phase I
Epic™ ICD	Phase I
Fortify™ ICD	Phase I
Fortify Assura™ ICD	Phase I
Nuance™ Pacemaker	Phase I
Photon™ ICD	Phase I

Device Name	Implementation Phase
Promote™ CRT-D	Phase I
Promote Accel™ CRT-D	Phase I
Promote Quadra™ CRT-D	Phase I
Quadra Allure™ CRT-P	Phase I
Quadra Allure MP™ CRT-P	Phase I
Quadra Assura™ CRT-D	Phase I
Quadra Assura MP™ CRT-D	Phase I
Unify™ CRT-D	Phase I
Unify Assura™ CRT-D	Phase I
Unify Quadra™ CRT-D	Phase I
Unify Quadra MP™ CRT-D	Phase I
Zenex™ Pulse Generator	Phase I
Zenus™ Pulse Generator	Phase I
Entrant™ ICD/CRT-D	Phase II
Gallant™ ICD/CRT-D	Phase II
Neutrino™ NxT ICD/CRT-D	Phase II
All Devices in Phase I & II	Phase III
Confirm Rx™ ICM	Phase IV
Jot Dx™ ICM	Phase IV

How am I able to receive alert notifications?

The Merlin.net PCN™ European cloud platform will be rolled out as part of a gradual series of LMRs. This means that not all features will be available during all LMR phases. Regarding DirectAlerts™, notifications can be received via email in LMR1 and LMR2. However, SMS text or phone call will be available in LMR3.

Will trended diagnostics and CorVue™ data be available?

The Merlin.net PCN European cloud platform will be rolled out as part of a gradual series of LMRs. This means that not all features will be available during all LMR phases. Regarding trended diagnostics and CorVue data, these will not be available during LMR1 and LMR2.

Why can't I see the "Device Under Advisory" column?

The Merlin.net PCN European cloud platform will be rolled out as part of a gradual series of LMRs. This means that not all features will be available during all LMR phases. The "Device Under Advisory" column is not visible during LMR1 and LMR2. For information about specific advisory details, please visit:

OUS - <https://www.cardiovascular.abbott/int/en/hcp/product-advisories.html>

U.S. - <https://www.cardiovascular.abbott/us/en/hcp/product-advisories.html>

Can the Communication Center be enabled for my clinic?

Although the Communication Center cannot be added during the LMR1 and LMR2, information about the connectivity of the transmitter can be found in the “Connectivity” column of the patient list or via quick links on the recent transmissions page. In LMR3, the Communication Center will be available again.

Am I able to share transmissions via the “Contact a Colleague” feature?

The “Contact a Colleague” feature is not available during LMR1 and LMR2. Transmissions can be printed to PDF within Merlin.net™ PCN and emailed to colleagues through your clinic email. In LMR3, the “Contact a Colleague” feature will be available again.

How can the profile be updated with the patient’s device change information?

If the patient’s implanted device is replaced during LMR1 or LMR2, the profile cannot be updated in the Merlin.net PCN European cloud platform. Please contact Remote Care Technical Support to submit a request for the update. After the profile has been updated, the transmitter will need to be paired to the new device.

Are implanting-only clinics included in the LMR?

No. Only clinics following their patients’ remote monitoring are participating in the LMR phases. Activator (implanting) clinics will not be included in the LMR phases.

Can a patient be transferred to another clinic during the LMR?

This cannot be done by the Merlin.net PCN European cloud platform user during LMR1 and LMR2. However, you can contact Remote Care Technical Support to submit a request for support to aid with the transfer. In LMR3, the Patient Transfer feature will be available again.

Is Electronic Health Records (EHR) integration available during the LMR?

During LMR1 and LMR2, the EHR integration will not be available. This can mean if you are using third-party solutions to integrate data, that this will not be possible for the new patients enrolled during these two LMR phases. However, from LMR3, the EHR integration will be available again.

For more information about the rollout, please consult the question, **“How will this rollout take place?”**.

Which browsers will work with the Merlin.net PCN European cloud platform?

If you are having difficulty loading the website or viewing information on the site, ensure you are either using Microsoft Edge or Google Chrome browsers on Windows 10.

Are there any existing Merlin.net PCN features that will be unavailable during the LMR phases?

There will be some features that will not be available on the Merlin.net PCN European cloud platform during LMR1 and LMR2 (see below); however, these features will be reinstated in the LMR3 phase:

Features:

- MerlinOnDemand™ (MOD)
- Notification via SMS
- DTV (DirectTrend™ Viewer)
- EHRDirect™ (Electronic Health Records)
- DirectCall™
- Device Under Advisory (BPA)
- Compliance Report
- Device Changeout
- Activator Clinic
- Patient Transfer (Release & Re-enroll)
No release is supported
- MLS (Multi Language Support)

For more details on the rollout, please consult the respective questions, **“How will this rollout take place?”**.

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Brief Summary: This product is intended for use by or under the direction of a Physician. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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