Janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

For Patients With Pulmonary Arterial Hypertension

Integrating **Patient Risk Assessment** Into Your CERNER® Electronic Health Record (EHR) System

Risk assessment is important in the management of pulmonary arterial hypertension (PAH). It aids in determining patient prognosis and monitoring response to treatment, and impacts treatment decisions. If widely integrated, risk assessment can help enhance consistency and timeliness of treatment, allowing for optimal care that can ultimately improve mortality while reducing morbidity in patients with PAH.[1,2]

The 2015 European Society of Cardiology (ESC)/European Respiratory Society (ERS) pulmonary hypertension guidelines strongly recommend a comprehensive, multidimensional risk assessment be conducted regularly in patients with PAH to guide treatment decisions.[3]

The 2015 ESC/ERS guidelines recommend performing appropriate follow-up risk assessments regularly every 3-6 months.[3]

Approaches to Risk Assessment

Different approaches are used to assess risk in patients with PAH, including the use of risk variables outlined according to 2015 ESC/ERS pulmonary hypertension guidelines; risk equations (ie, French PAH Registry and National Institutes of Health [NIH] equations); or use of risk score (ie, REVEAL [Registry to Evaluate Early and Long-term PAH Disease Management] registry risk score).[1,3-6] Risk scores and equations have been developed by assessing variables collected from PAH registries to analyze the course of disease based on current treatments.[1]

Why REVEAL 2.0 and/or REVEAL Lite 2?

REVEAL 2.0, which incorporates new variables and expanded thresholds from REVEAL 1.0, was developed to improve risk discrimination. To expedite risk assessment in the clinic and to address the barriers leading to suboptimal risk assessment, a simplified risk calculator, REVEAL Lite 2, was developed. REVEAL Lite 2 is a simplified version of the REVEAL 2.0 Risk Calculator that uses 6 exclusively noninvasive and modifiable variables for routine clinical implementation. It is intended to complement rather than replace REVEAL 2.0.[7]

Risk Assessment Concerns and Barriers

A retrospective chart analysis* of patients considered low risk by gestalt showed that[8]:

11%-36%
were categorized as **intermediate risk** using various formal assessment tools (n=63 and 47, respectively)[8]

4%-28%
were categorized as **high risk** using various formal assessment tools (n=46 and 47, respectively)[8]

In a separate survey,[†] **41% (50/121) of treatment decision-makers** reported not using a formal tool to assess risk in patients with PAH[9]

▶ **90% of these decision-makers** reported that they relied on gestalt[9]

*Medical charts of 153 patients with FC II PAH were retrospectively analyzed to compare the results of risk assessment by clinical gestalt to those of the COMPERA, modified noninvasive FPHR, and REVEAL 2.0 tools.[8]

†One hundred twenty-one PAH treatment decision-makers (physicians, nurse practitioners, and physician assistants) in the United States were surveyed between February 7 and March 10, 2019, on their utilization of formal risk assessment tools in PAH management in clinical practice settings. Respondents could report using only clinical gestalt for risk assessment or choose from a number of formal risk assessment tools, including the REVEAL risk calculator, the French Pulmonary Hypertension Registry (FPHR) risk scoring system, the European Society of Cardiology (ESC)/European Respiratory Society (ERS) Guidelines for risk assessment, Comparative Prospective Registry of Newly Initiated Therapies for Pulmonary Hypertension (COMPERA) risk stratification, the Swedish Pulmonary Arterial Hypertension Registry (SPAHR) risk assessment, or another tool (unspecified). Medical writing support was funded and sponsored by Actelion Pharmaceuticals Ltd. Of treatment decision-makers surveyed, 41% (50/121) reported not using formal PAH risk assessment tools.[9,10]

Risk Assessment Concerns and Barriers (continued)

In a survey of 121 PAH treatment decision-makers, **only 59% of decision-makers reported using risk assessment tools.**[9]*

Most commonly cited barriers to increased use of risk tools by subgroups[9]						
Subgroup	Lack of technology/ EMR integration n (%)	Lack of administrative/ colleague support n (%)	Clarity on which tool to use n (%)	Time constraints n (%)	Complexity of tools and scoring systems n (%)	Lack of education/ awareness/training n (%)
Use risk tools (n=71)	24 (34)	11 (15)	15 (21)	30 (42)	9 (13)	4 (6)
DON'T USE risk tools (n=46)	17 (37)	13 (28)	12 (26)	21 (46)	8 (17)	7 (15)
The lack of technology/electronic medical record integration was cited as one of the most common barriers to increased use of risk tools.						

Decision-makers suggested electronic medical record integration, online risk calculators, pop-up reminders, and automated population of risk calculators with patient data as ways to increase the use of risk assessment tools.[9]

*One hundred twenty-one PAH treatment decision-makers (physicians, nurse practitioners, and physician assistants) in the United States were surveyed between February 7 and March 10, 2019, on their utilization of formal risk assessment tools in PAH management in clinical practice settings. Respondents could report using only clinical gestalt for risk assessment or choose from a number of formal risk assessment tools, including the REVEAL risk calculator, the French Pulmonary Hypertension Registry (FPHR) risk scoring system, the European Society of Cardiology (ESC)/European Respiratory Society (ERS) Guidelines for risk assessment, Comparative Prospective Registry of Newly Initiated Therapies for Pulmonary Hypertension (COMPERA) risk stratification, the Swedish Pulmonary Arterial Hypertension Registry (SPAHR) risk assessment, or another tool (unspecified). Medical writing support was funded and sponsored by Actelion Pharmaceuticals Ltd. Of treatment decision-makers surveyed, 41% (50/121) reported not using formal PAH risk assessment tools.[9,10]

PAH Risk Assessment Solution

▶ REVEAL 2.0, which incorporates new variables and expanded thresholds from REVEAL 1.0, was developed to improve risk discrimination

▶ To expedite risk assessment in the clinic and to address the barriers leading to suboptimal risk assessment, a simplified risk calculator, REVEAL Lite 2, was developed.[7] REVEAL Lite 2 is intended to complement rather than replace REVEAL 2.0

▶ This guide provides step-by-step instructions to assist in the development and implementation of the REVEAL 2.0 and REVEAL Lite 2 risk score calculators and clinical decision support (CDS) alert to your organization's EHR

References: 1. Raina A, Humbert M. Risk assessment in pulmonary arterial hypertension. *Eur Respir Rev*. 2016;25(142):390-398. **2.** Hoffman KK, Benza RL, Kanwar M. Risk stratification in PAH. American College of Cardiology. Published online January 31, 2019. Accessed January 11, 2021. https://www.acc.org/latest-in-cardiology/articles/2019/01/31/11/10/risk-stratification-in-pah. **3.** Galiè N, Humbert M, Vachiery JL, et al. 2015 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. The Joint Task Force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS): Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT). *Eur Heart J*. 2016;37(1):67-119. **4.** Humbert M, Sitbon O, Yaici A, et al. Survival in incident and prevalent cohorts of patients with pulmonary arterial hypertension. *Eur Respir J*. 2010;36(3):549-555. **5.** D'Alonzo GE, Barst RJ, Ayres SM, et al. Survival in patients with primary pulmonary hypertension. Results from a national prospective registry. *Ann Intern Med*. 1991;115(5):343-349. **6.** Benza RL, Gomberg-Maitland M, Miller DP, et al. The REVEAL registry risk score calculator in patients newly diagnosed with pulmonary arterial hypertension. *Chest*. 2012;141(2):354-362. **7.** Benza RL, Kanwar MK, Raina A, et al. Development and validation of an abridged version of the REVEAL 2.0 risk score calculator, REVEAL Lite 2, for use in patients with pulmonary arterial hypertension *Chest*. 2021;159(1):337-346. **8.** Sahay S, Tonelli A, Selej M, et al. Risk assessment in patients with functional class II pulmonary arterial hypertension: comparison of physician gestalt with ESC/ERS and the REVEAL 2.0 risk score. *PLoS One*. 2020;15(11):e0241504. **9.** Wilson M, Keeley J, Kingman M, Wang J, Rogers F. Current clinical utilization of risk assessment tools in pulmonary arterial hypertension: a descriptive survey of facilitation strategies, patterns, and barriers to use in the United States. *Pulm Circ*. 2020;10(3);1-10. **10.** Supplement: Wilson M, Keeley J, Kingman M, Wang J, Rogers F. Current clinical utilization of risk assessment tools in pulmonary arterial hypertension: a descriptive survey of facilitation strategies, patterns, and barriers to use in the United States. *Pulm Circ*. 2020;10(3);1-10.

Important Considerations

- The instructions listed in this guide are for use on the Cerner® platform. Although the instructions have been tested on this EHR system, they are not guaranteed to work for all available software versions. These materials have not been reviewed or endorsed by Cerner®

- The user is solely responsible for the implementation, testing, and monitoring to ensure proper orientation in the EHR system. Janssen does not take responsibility to revise these instructions as the software or recommendations change

- Capabilities vary based on each individual EHR system. Please refer to the instructions provided for potential limitations related to your system

- **Minimum Required Version of Cerner®:** This guide assumes that the organization is using the **Cerner® Millennium 2018 software or later**

- **Build Complexity: Easy (from 2 to 4 hours per resource).** The time estimate includes all the build steps, configuration, and testing typically required prior to implementing new changes within a specific environment
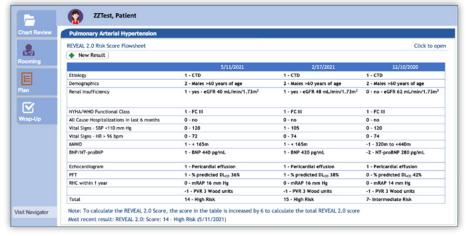
- This build guide outlines how to build a PAH Risk Assessment based on REVEAL 2.0 and REVEAL Lite 2

- REVEAL Lite 2 is a simplified version of the REVEAL 2.0 Risk Calculator that uses 6 exclusively noninvasive and modifiable variables for routine clinical implementation. It is intended to complement rather than replace REVEAL 2.0

- This build guide is not intended to replace your health system's processes or protocols

- Note that some modifications to the build may be required to accommodate use in certain areas (eg, emergency department, outpatient clinics)

- In each clinical category or clinical sub-category of the build guide, your organization may choose to place additional orders to meet the needs of its internal protocols or guidelines

- Ultimately, it is the responsibility of the healthcare provider to select a treatment based on their independent medical judgment and the needs of each individual patient

Adding the REVEAL 2.0 Calculator to the EHR

The process outlined in this resource is variable, and not all steps will apply to every health system. Any steps or settings that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools.

The steps describe how to access and/or create the REVEAL 2.0 Risk Score Calculator. The instructions are not intended to replace your health system's processes or protocols, and are not intended to be an endorsement or recommendation of Cerner® or REVEAL 2.0. Any decision related to patient care should be made by their healthcare provider(s).

Note: This is mock patient data.

About the REVEAL 2.0 Calculator

The risk calculator includes two key sections and a scoring mechanism as follows:

Section 1: The questions

Each question is individually scored.

Section 2: The results

All individual results are added up to calculate the REVEAL 2.0 Risk Score.

The interpretation of the risk score results: | **Low risk:** 0 to 6 | **Intermediate risk:** 7 to 8 | **High risk:** ≥9

Many abbreviations are used in the REVEAL 2.0 Risk Calculator. Below is a summary of the abbreviations:

6MWT: 6-minute walk test

BNP: brain natriuretic peptide

CTD: connective tissue disease

DLco: diffusing capacity of the lungs for carbon monoxide

eGFR: estimated glomerular filtration rate

FC: functional class

mRAP: mean right atrial pressure

NT-proBNP: N-terminal pro-brain natriuretic peptide

NYHA: New York Heart Association

PAH: pulmonary arterial hypertension

PFT: pulmonary function test

PoPH: portopulmonary hypertension

PVR: pulmonary vascular resistance

REVEAL: Registry to Evaluate Early and Long-Term Pulmonary Arterial Hypertension Disease Management

WHO: World Health Organization

Build Guide

Administrative rights are usually required to access this functionality.

Step 1 – Create DTAs

Confirm if discrete task assays (DTAs) are available to capture REVEAL 2.0 structured data. If none are available, follow the steps below:

1. Launch **DCPTools.exe** to access the **DTA Wizard**

2. Review if DTAs are available for the data elements. If DTAs are not available, create the DTAs listed in the table below. Click **OK** once completed

3. Create a new DTA with the same Unique Mnemonic and Description for the **REVEAL 2.0 Risk Score**. Set the **Result** type to **Calculation** and select the **Equation** button. Enter the newly created DTAs above (*6 + Etiology + Demographics + Comorbidities + NYHA or WHO FC + ...*) **Note:** To calculate the REVEAL 2.0 PAH Risk Score, all result values are added up and increased by 6 to find the total risk score. Press **OK** once completed

4. Associate the **Event Codes** by clicking on the **binoculars** icon. Click **Apply** to complete the DTA creation process

DTA Description / DTA Mnemonic	DTA Result Type	Alpha Responses	Alpha Result Value
Etiology	Alpha	CTD	1
		PoPH	3
		Heritable PAH	2
Demographics	Alpha	Males >60 years of age	2
Comorbidities	Alpha	eGFR <60 mL/min/1.73 m^2, or renal insufficiency defined by clinical judgment if eGFR is not available	1
NYHA or WHO FC	Alpha	FC I	-1
		FC III	1
		FC IV	2
All-cause hospitalizations in last 6 months	Alpha	Yes	1
Vital Signs	Multi	Systolic blood pressure <110 mm Hg	1
		Heart rate >96 beats/min	1
6MWT	Alpha	≥440 m	-2
		320 m to <440 m	-1
		<165 m	1
BNP/NT-proBNP	Alpha	BNP <50 pg/mL or NT-proBNP <300 pg/mL	-2
		BNP 200 pg/mL to <800 pg/mL	1
		BNP ≥ 800 pg/mL or NT-proBNP ≥1100 pg/mL	2
Echocardiogram	-	Pericardial effusion	1
PFT	-	% predicted DL$_{CO}$ <40%	1
RHC	Multi	mRAP ≥20 mm Hg within 1 year	1
		PVR <5 Wood units	-1
REVEAL 2.0 Risk Score	Calculation	Equation (previous rows + 6)	-

Build Guide (continued)

Administrative rights are usually required to access this functionality.

Step 2 – Create the REVEAL 2.0 Risk Score Calculator PowerForm

1. Launch **DCPTools.exe** to access the **PowerForm** Tool

2. Create a Form Section by clicking **Section>New**

3. Enter a Section Name and Section Display based on the organization's naming conventions, for example *"REVEAL 2.0 PAH Risk Score Calculator"*, and click **OK**

4. Drag 11 **Alpha Boxes** for the first 2 DTAs created in step 1: Create DTAs

5. Right-click the **Alpha Boxes** and associate it to the **DTAs**

6. Drag the last **Alpha Box** for the last DTA created in Step 1: **Create DTAs (REVEAL 2.0 Risk Score)**

7. Right-click the **Alpha Boxes** and associate it to the **DTAs**

8. Set a **Header** and label it *"REVEAL 2.0 PAH Risk Score"*

9. Drag a label from the tool box in the section under the Section. Enter:
   › **Low risk:** *"0 to 6"*
   › **Intermediate risk:** *"7 to 8"*
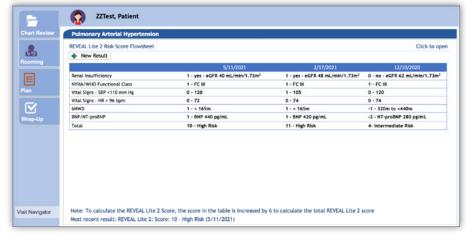   › **High risk:** *"≥9"*

10. Create a new **Form** to contain the sections created above and enter *"REVEAL 2.0 PAH Risk Score"* for the name

11. Plug the sections in the new **Form** and click **File>Save**

Adding the REVEAL Lite 2 Calculator to the EHR

The process outlined in this resource is variable, and not all steps will apply to every health system. Any steps or settings that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools.

The steps describe how to access and/or create the REVEAL Lite 2 Risk Score Calculator. The instructions are not intended to replace your health system's processes or protocols, and are not intended to be an endorsement or recommendation of Cerner® or REVEAL Lite 2. Any decision related to patient care should be made by their healthcare provider(s).

Note: This is mock patient data.

About the REVEAL Lite 2 Calculator

The risk calculator includes two key sections and a scoring mechanism as follows:

Section 1: The questions

Each question is individually scored.

Section 2: The results

All individual results are added up to calculate the REVEAL Lite 2 Risk Score.

The interpretation of the risk score results: **Low risk:** 1 to 5 | **Intermediate risk:** 6 to 7 | **High risk:** ≥8

Many abbreviations are used in the REVEAL Lite 2 Risk Calculator. Below is a summary of the abbreviations:

6MWT: 6-minute walk test

BNP: brain natriuretic peptide

CTD: connective tissue disease

DLco: diffusing capacity of the lungs for carbon monoxide

eGFR: estimated glomerular filtration rate

FC: functional class

mRAP: mean right atrial pressure

NT-proBNP: N-terminal pro-brain natriuretic peptide

NYHA: New York Heart Association

PAH: pulmonary arterial hypertension

PFT: pulmonary function test

PoPH: portopulmonary hypertension

PVR: pulmonary vascular resistance

REVEAL: Registry to Evaluate Early and Long-Term Pulmonary Arterial Hypertension Disease Management

WHO: World Health Organization

Build Guide

Administrative rights are usually required to access this functionality.

Step 1 – Create DTAs

Confirm if discrete task assays (DTAs) are available to capture REVEAL Lite 2 structured data. If none are available, follow the steps below:

1. Launch **DCPTools.exe** to access the **DTA Wizard**

2. Review if DTAs are available for the data elements. If DTAs are not available, create the DTAs listed in the table to the right. Click **OK** once completed

3. Create a new DTA with the same Unique Mnemonic and Description for the REVEAL Lite 2 Risk Score. Set the **Result** type to **Calculation** and select the **Equation** button. Enter the newly created DTAs above (*6 + Comorbidities + NYHA or WHO FC + ...*) **Note:** To calculate the REVEAL Lite 2 PAH Risk Score, all result values are added up and increased by 6 to find the total risk score. Press **OK** once completed

4. Associate the **Event Codes** by clicking on the **binoculars** icon. Click **Apply** to complete the DTA creation process

DTA Description / DTA Mnemonic	DTA Result Type	Alpha Responses	Alpha Result Value
Comorbidities	Alpha	eGFR <60 mL/min/1.73 m², or renal insufficiency defined by clinical judgment if eGFR is not available	1
NYHA or WHO FC	Alpha	FC I	-1
		FC III	1
		FC IV	2
All-cause hospitalizations in last 6 months	Alpha	Yes	1
Vital Signs	Multi	Systolic blood pressure <110 mm Hg	1
		Heart rate >96 beats/min	1
6MWT	Alpha	≥440 m	-2
		320 m to <440 m	-1
		< 165 m	1
BNP/NT-proBNP	Alpha	BNP <50 pg/mL or NT-proBNP <300 pg/mL	-2
		BNP 200 pg/mL to <800 pg/mL	1
		BNP ≥800 pg/mL or NT-pro BNP ≥1100 pg/mL	2
REVEAL 2.0 Risk Score	Calculation	Equation (previous rows + 6)	-

Build Guide (continued)

Administrative rights are usually required to access this functionality.

Step 2 – Create the REVEAL Lite 2 Risk Score Calculator PowerForm

1. Launch **DCPTools.exe** to access the **PowerForm** Tool

2. Create a **Form Section** by clicking **Section>New**

3. Enter a Section Name and Section Display based on the organization's naming conventions, for example, *"REVEAL Lite 2 PAH Risk Score Calculator",* and click **OK**

4. Drag 5 **Alpha Boxes** for the first 2 DTAs created in Step 1: Create DTAs

5. Right-click the **Alpha Boxes** and associate it to the DTAs

6. Drag the last **Alpha Box** for the last DTA created in Step 1: Create DTAs (REVEAL Lite 2 PAH Risk Score)

7. Right-click the **Alpha Boxes** and associate it to the DTAs

8. Set a **Header** and label it *"REVEAL Lite 2 PAH Risk Score"*

9. Drag a label from the tool box in the section under the Section. Enter:
   › **Low risk:** *"1 to 5"*
   › **Intermediate risk:** *"6 to 7"*
   › **High risk:** *"≥8"*

10. Create a new **Form** to contain the sections created above and enter *"REVEAL Lite 2 PAH Risk Score"* for the name

11. Plug the sections in the new **Form** and click **File>Save**

Creating a Clinical Decision Support (CDS) Alert in the EHR

▸ The steps describe how to access and/or create a CDS Alert in the EHR

▸ The process outlined in this resource is variable, and not all steps will apply to every health system

▸ Any steps or settings that are not part of a health system's standard process should be excluded or modified accordingly

▸ Any questions should be directed to the appropriate service provider

▸ The practice is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools

▸ The instructions are not intended to replace your health system's processes or protocols, and are not intended to be an endorsement or recommendation of Cerner® or REVEAL

▸ Any decision related to patient care should be made by their healthcare provider(s)

About the CDS Alert

An EHR Alert creates a reminder for the clinical staff and displays suggested follow-up recommendations to the end user. The CDS Alert is triggered by the patient's age and diagnosis suggesting PAH.

Suggested CDS Alert criteria

ICD-10 codes for PAH:
I27.0 Primary pulmonary hypertension
I27.20 Pulmonary hypertension, unspecified
I27.21 Secondary pulmonary arterial hypertension

Age: 18 years and older

Build Guide

Cerner®'s CDS solution, a Discern Alert, may be created or customized to align with the health system's clinical preferences and workflow. A Discern Alert creates a reminder for the clinical staff and displays suggested follow-up recommendations to the end user.

1 Launch **DiscernDev.exe** or **DiscernLaunch.exe** (Expert Knowledge Module)

2 Complete the desired name, for example *"REVEAL 2.0"* or *"REVEAL Lite 2"*

3 Set the status to **testing**

4 Create the Evoke section parameters:

  a. E1:

    i. Select **OPENCHART**

    ii. Select **EKS_APPLICATION_E** and select for **Application** select **HNA: Powerchart**

  b. E2:

    i. Select **OPENCHART**

    ii. Select **EKS_USER_POSITION_E** and for **POSITION** select the desired Specialty, Department and Provider Type (for example, **Pulmonology, Cardiology, Primary Care, Internal Medicine, Family Medicine,** etc.) and set the desired role types (for example, **clinician, nurse practitioner, physician assistant,** etc.)

5 Set the **Logic** section parameters:

  a. E1:

    i. Select **EKS_AGE_EVAL_L,**

    ii. Set to **Where Person's Age is greater than 18**

  b. E2:

    i. Select **EKS_DIAGNOSIS_FIND_L**,

    ii. Set the **OPT_DIAGNOSIS** to **PAH** (ICD-10 codes: I27.0, I27.20 and I27.21)

6 Finally set the **Action** section parameters:

  a. If a text alert is preferred, select **EKS_ALERT_FLEX_A.E**

  b. Set the logic to **L1 AND L2**

  c. Enter the following message for TXT: *"The REVEAL 2.0/REVEAL Lite 2 Risk Calculator is available to help predict mortality risk for PAH patients."*

  d. Set to the **REVEAL 2.0** or **REVEAL Lite 2 Flowsheet**

7 Test the new alert, cycle the Discern servers, and activate and release once satisfactory testing has been completed