*Trust in Data*

# Site Visits at Risk? Your Plan B.

## Mitigate Coronavirus side-effects with RBQM

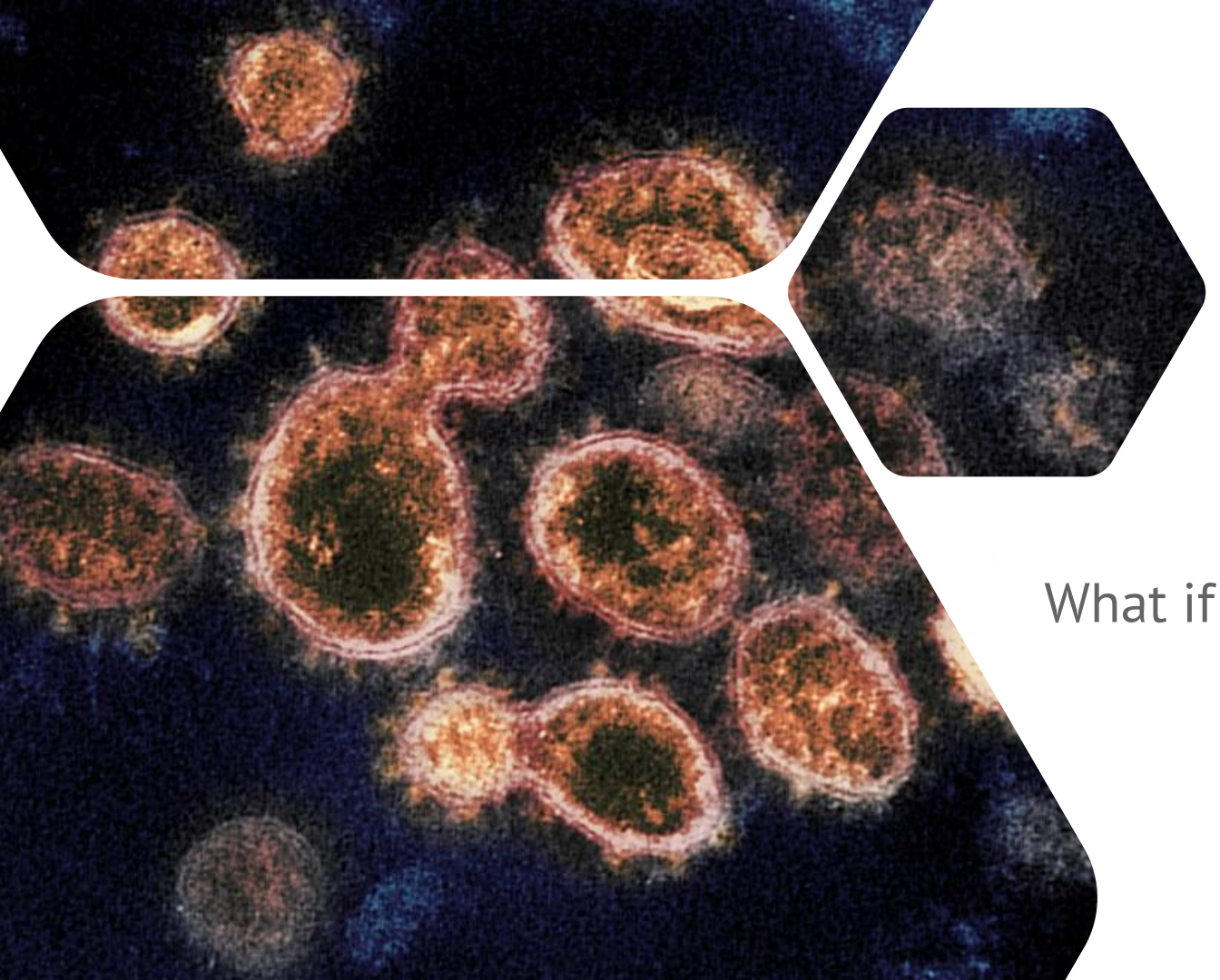
Cyntegrity | Monday, March 9, 2020


*Chinese **'patients are simply not going'** to clinical trial sites, IQVIA warns*

*AbbVie, GSK, Sanofi and more **limit employee travel** as coronavirus threatens business*

*Coronavirus: Dutch **hospital closed** after treating IC patient*

*Craig Lipset, former head of Clinical Innovation at Pfizer*



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# COVID-19

## What if you can no longer visit your sites?

## AT RISK

- Patient safety
- Study quality
- Study timelines

## ASSESS THE RISK

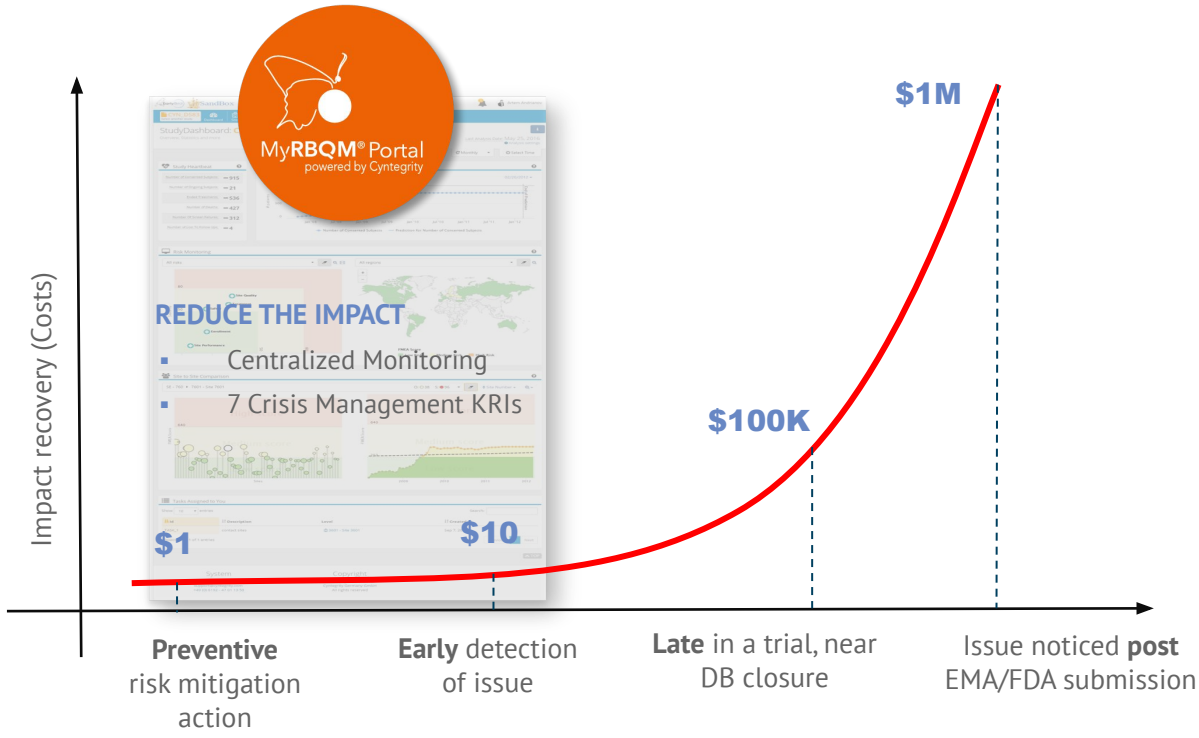
- Continue monitoring remotely
- Get daily updates


## REDUCE THE IMPACT

- Centralized Monitoring
- 7 'Crisis Management' KRIs

# What if you can no longer visit your sites?

*Mitigate, before it's too late*



## Scenario 1: Patient in hospital, monitor blocked

- The hospital has been put under quarantine
- You run a study in that clinic / hospital and your patients are in the clinic
- Your monitors cannot enter the hospital
- Hospital staff cannot see the monitor in person

## Scenario 2: Outpatients and monitor blocked

- The hospital has been put under quarantine
- You run a study in a clinic / hospital and your patients are outpatients
- Your monitors and your patients cannot access the hospital
- Hospital staff cannot see the monitor in person
- Your patients cannot access treatment

## Scenario 3: Patients cannot meet physicians in person

- Your patients have been put under quarantine
- You run a study in a private practice or your patients are outpatients
- Your patients cannot meet their physician in person
- Your patients cannot access treatment

## KRI Set to Monitor Impact COVID-19

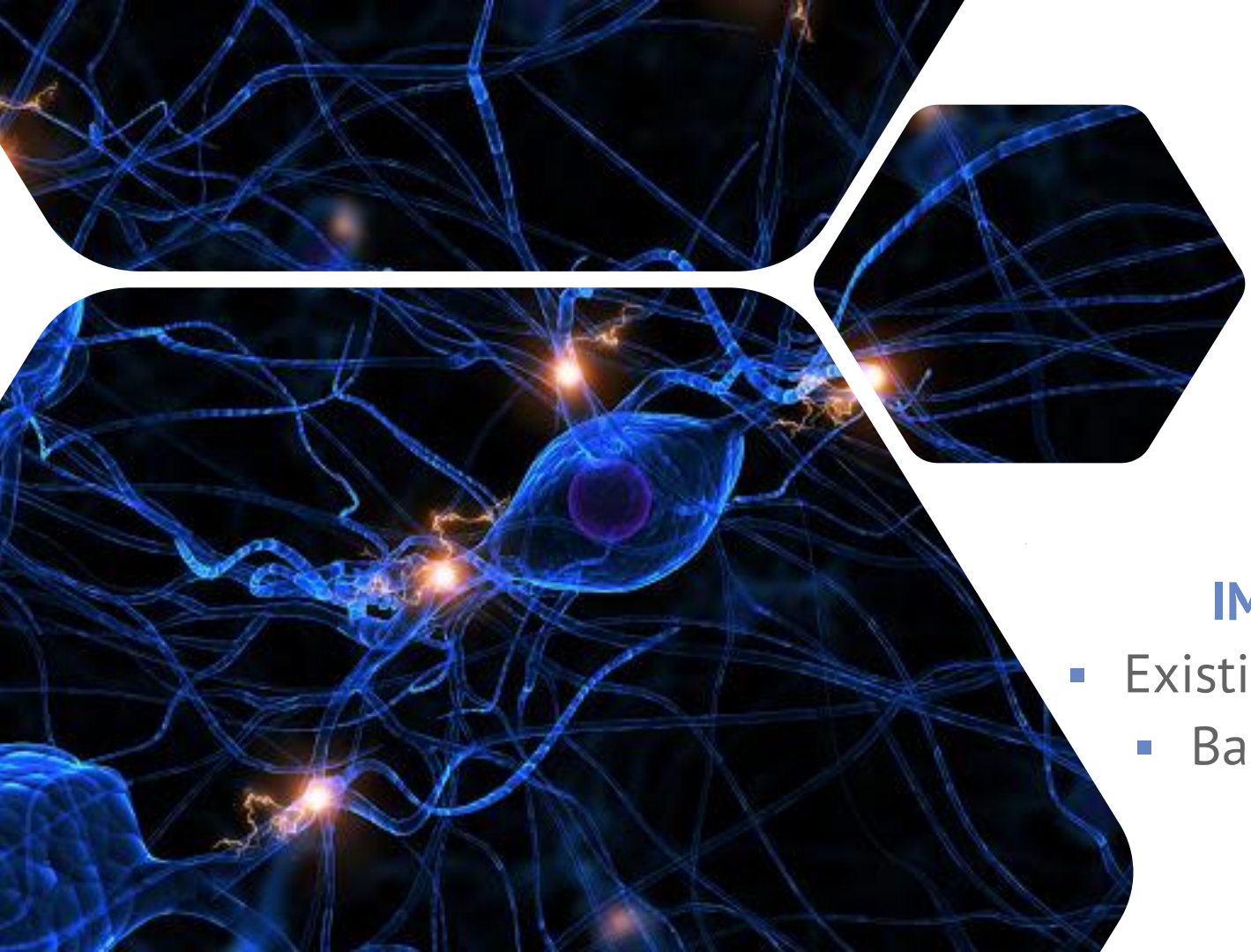
1. Under / Over- Enrollment
2. Patient Adherence to Medications
3. AEs / SAEs level too low or too high compared to the previous period
4. % of missing values in the important data items is too high
5. High level of dropouts / informed consent withdrawn
6. Abnormal patterns in lab values for any trends indicating an additional burden to the patients
7. Large gap between data generation and data entry

## BETTER ACT NOW

- MyRBQM® Crisis-kit
- Within 3 weeks you're ready to go

## WE ACT FAST

- Data connectors in place
- Daily data analysis



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# RISK-FREE IMPLEMENTATION

- Existing infrastructure
  - Based on read-only

# Scenario 1: Patient in hospital, monitor blocked

- The hospital has been put under quarantine
- You run a study in that clinic / hospital and your patients are in the clinic
- Your monitors cannot enter the hospital
- Hospital staff cannot see the monitor in person

**KRIs for this scenario**

1. Check the number of adverse events / serious adverse events
   - numbers going up is an indicator that the infection may influence the safety of the patients
   - numbers going down is an indicator that the site staff may be overwhelmed with other tasks and cannot take care of the documentation

**Mitigation actions**

- check with sites remotely on the reason for the change in adverse events
- consider terminating patients' participation in the study prematurely
- consider stopping or slowing down enrollment for a limited time

# Scenario 1: Patient in hospital, monitor blocked

- The hospital has been put under quarantine
- You run a study in that clinic / hospital and your patients are in the clinic
- Your monitors cannot enter the hospital
- Hospital staff cannot see the monitor in person

**KRIs for this scenario**

2. Check the number of missing values in the important data items
    - numbers remain stable, no concerns
    - numbers going up, staff may have too much work and more important objectives
    - numbers going down, situation seems to be under control

**Mitigation actions**

- check with sites remotely on the reason for the missing data (data entry problems or data not generated)
- consider hiring hospital external staff to enter the data remotely, if available, with access to the electronic patient record
- consider a protocol amendment to reduce the overall number of visits and data items to be generated and captured

# Scenario 1: Patient in hospital, monitor blocked

- The hospital has been put under quarantine
- You run a study in that clinic / hospital and your patients are in the clinic
- Your monitors cannot enter the hospital
- Hospital staff cannot see the monitor in person

**KRIs for this scenario**

3. Check the number of dropouts / informed consent withdrawn
    - numbers going up is an indicator that the infection / hospital situation is an extra burden to the patients
    - numbers going down or remaining stable probably means not to worry

**Mitigation actions**

- check with sites remotely on the reasons for patients dropping out
- consider lowering the patient burden by reducing the number of examinations
- check for certain interactions potentially explaining the increasing number of dropouts

# Scenario 1: Patient in hospital, monitor blocked

- The hospital has been put under quarantine
- You run a study in that clinic / hospital and your patients are in the clinic
- Your monitors cannot enter the hospital
- Hospital staff cannot see the monitor in person

**KRIs for this scenario**

4. Check the lab values for any trends indicating an additional burden to the patients
    - lab values are ranging within the same boundaries as prior to the quarantine is positive
    - lab values are ranging outside, i.e. significantly lower / higher than prior to the quarantine, patient may suffer from a coronavirus infection

**Mitigation actions**

- check for drug - drug interactions and potentially terminate patient participation
- consider a protocol amendment and a study drug dosage lowering for a limited time

# Scenario 1: Patient in hospital, monitor blocked

- The hospital has been put under quarantine
- You run a study in that clinic / hospital and your patients are in the clinic
- Your monitors cannot enter the hospital
- Hospital staff cannot see the monitor in person

**KRIs for this scenario**

5. Analyse the time between data generation and data entry
    - data are being entered much later than in the pre-Coronavirus period and patient safety may be compromised
    - data are entered not differently than in the pre-Coronavirus period

**Mitigation actions**

- ask site to at least enter the safety data and enter any other data at a later point in time
- consider remote data entry outside of the hospital if access to patient records can be granted remotely

# Scenario 2: Outpatients and monitor blocked

- The hospital has been put under quarantine
- You run a study in a clinic / hospital and your patients are outpatients
- Your monitors and your patients cannot access the hospital
- Hospital staff cannot see the monitor in person
- Your patients cannot access treatment

**KRIs for this scenario**

1. Analyse the number of adverse events / serious adverse events ( and all other cases described in scenario 1 since they are all requiring the same / similar mitigation actions)

**Mitigation actions**

- check with sites remotely on the reason for the change in adverse events
- consider hiring external medical staff / study nurses that could visit the patients and document the findings
- grant EDC access to external / new staff for data entry of safety data
- consider setting up video consultation between the patient and the study investigator
- worst case, consider opening another site in the same region and transfer responsibilities to such a new site

# Scenario 3: Patients cannot meet physicians in person

- Your patients have been put under quarantine
- You run a study in a private practice or your patients are outpatients
- Your patients cannot meet their physician in person
- Your patients cannot access treatment

**KRIs for this scenario**

1. Check the number of adverse events / serious adverse events
    - numbers going up is an indicator that the infection may influence the safety of the patients
    - numbers going down is an indicator that the patient worries about other things than study drug related adverse events

**Mitigation actions**

- check with sites remotely on the reason for the change in adverse events
- consider hiring external medical staff / study nurses that could contact the patients remotely and document the findings
- grant EDC access to external / new staff for data entry of safety data
- consider setting up video consultation between the patient and the study investigator

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- Your patients have been put under quarantine
- You run a study in a private practice or your patients are outpatients
- Your patients cannot meet their physician in person
- Your patients cannot access treatment

**KRIs for this scenario**

2. Check the number of missing values in the important data items
    - numbers remain stable, no concerns
    - numbers going up, patient does not see the site
    - numbers going down, situation seems to be under control

**Mitigation actions**

- consider hiring staff that could see the patient at home and take for example a blood sample, measure blood pressure, check on AEs etc
- have the external staff enter the data into the EDC system
- consider terminating the patient participation in the study

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**KRIs for this scenario**

3. Check the number of dropouts / informed consent withdrawn
    - numbers going up is an indicator that the infection is an extra burden to the patients
    - numbers going down or remaining stable probably means not to worry

**Mitigation actions**

- consider a protocol amendment and terminate the study participation for infected patients
- consider hiring external staff to motivate the patients to stay in the study, as far as that is possible

## Scenario 3: Patients cannot meet physicians in person

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## “Your Plan B.” Package

*Mitigate Coronavirus side-effects with RBQM*

### | Setup

- ➔ One-time fee
- ➔ Includes: data connection, special COVID-19 KRI-set (7 KRIs), 1-day remote train-the-trainer training, system testing.

### | User License

- ➔ Monthly fee
- ➔ Includes: **MyRBQM® Portal**, special COVID-19 KRI-set (7 KRIs), 20 seats.

### | eCourse

- ➔ At no charge
- ➔ Includes: The **White Belt' training** is dedicated to the fundamental RBQM knowledge you and your team must have before developing your RBQM strategy, 20 enrollments.

**CONTACT US FOR PRICING**

## CONTACT US


**e**: post@cyntegrity.com
**t**: +49 (0) 6192-470-113-50
**m**: +1 415.505.5802