Contents

What's Si...   ...se 5.0

...patients entering trials by...   ...data for March and April

...patients entering trials by country and...   ...ed (full month data for March and April

...regulatory response/guidance
...ole of the current 8 vaccine clinical trials for COVID-19
...olution

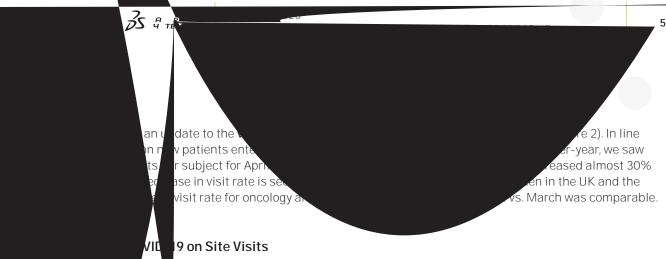## ...to Ongoing Data Capture in Clinical Trials

...tinuously monitoring the global impact of COVID-19 on clinical trials. Our first data and insights impact ...eased on March 23, with subsequent releases on April 3, April 17 and May 4. Medidata's analysis of the ...w patients entering clinical trials for actively recruiting studies demonstrates the growing significance of the ...mpact on cities, regions, and countries, with increasingly tighter laws and guidelines restricting movement by ...tside of the home.

...s to the April 3, April 17 and May 1 analyses were performed on May 15, and the results for the first two weeks of ...re shown next to April (See Figure 1). Currently, the global data shows a 74% decrease in the average number of ...patients entering trials per study-site year-over-year during the first two weeks of May compared to the same time ...me last year.[1] The impact year-over-year for the first two weeks of May as compared to April is similar, and shows the ...andemic continues to have an effect on trial activity and new patients entering trials.
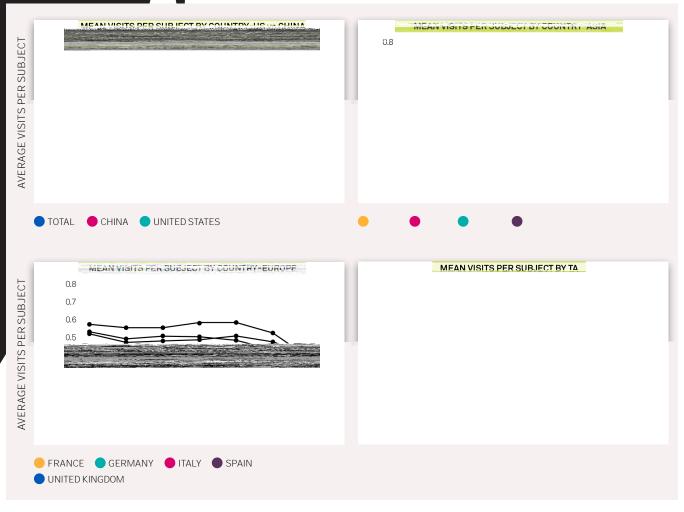

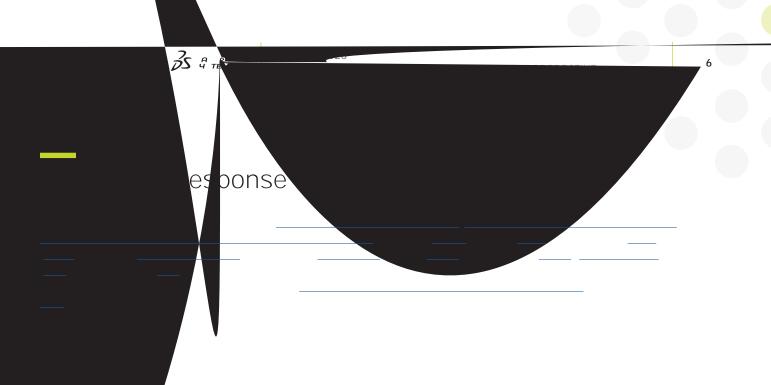[1] Analysis across 4,667 studies and 186,807 study-sites

...an update to the ... ...re 2). In line
...on new patients ente... ...r-year, we saw
...ts per subject for Apr... ...eased almost 30%
...ase in visit rate is see... ...en in the UK and the
... ...visit rate for oncology a... ...vs. March was comparable.

...VID-19 on Site Visits

MEAN VISITS PER SUBJECT BY COUNTRY–US vs CHINA

AVERAGE VISITS PER SUBJECT

● TOTAL   ● CHINA   ● UNITED STATES

MEAN VISITS PER SUBJECT BY COUNTRY – ASIA

0.8

●   ●   ●   ●

MEAN VISITS PER SUBJECT BY COUNTRY–EUROPE

AVERAGE VISITS PER SUBJECT

0.8
0.7
0.6
0.5

● FRANCE   ● GERMANY   ● ITALY   ● SPAIN
● UNITED KINGDOM

MEAN VISITS PER SUBJECT BY TA

Understanding what is happening on the ground is critical to define a path forward. We will continue to publish updated analyses on overall industry trends throughout this pandemic and beyond.

esponse

health is depende... op readily ...id virus and antibod... er prevent ...s mitigate the likelihood... he World Health ...vaccine candidates in pr... es for COVID-19 in ... summary of these vacci... n Figure 3 below.

...19 Vaccines in Clinical Development

lutions to Trials

...be immediately leveraged by ... understand the impact of ... and to mitigate the challenges of pati... ...sit sites for their drugs and protocol-...t-r...orted data capture.

...ories of challenges facing clinical trials. The following is a high level summary of these ...ons that Medidata is prepared and ready to provide:

CHALLENGE 1: UNDERSTANDING THE EVOLVING SITUATION

...evel metrics and dashboards to understand impact on enrollment, patient visits, data collection, query

...ew and Ac...

...ls about the Medidat... ...trial challenges. Since ...es are not mutually excl... ...e to more than one challenge.

CHALLENGE 1: UNDERSTANDING THE EVOLVING SITUATION

| ...ials

CHALLENGE	SOLUTION
...y/site/ ...ss the ...g risk ...y plans	**COVID-19 Trial Impact Analytics***: Data and analytics to develop industry tracking, forecasting and deep dives for priority studies to support client's COVID-19 impact assessment, risk mitigation and recovery decisions.

Real-time Situation Insights: Inform critical decisions on where to focus efforts by benchmarking impact of COVID-19 on own trials vs. industry
- Assess impact of COVID-19 on own trials and compare to industry via standard dashboards
- Understand weekly and monthly trends, and year-over-year performance for subject accrual, visits and data quality measures
- Views at portfolio, study, country/region and site level

Impact & Recovery Forecasting: Plan ahead by understanding leading indicators of slowdown and recovery at a country and site level
- Track country/region and site level performance to understand countries and sites that are coming back on-line
- Overlay trends in COVID-19 testing and infection rates with impact on trials to identify leading indicators of recovery at a country / region / site level

...ledidata Solution

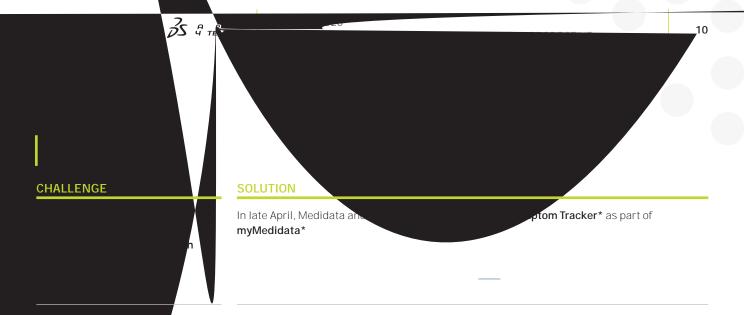## CHALLENGE 2: RECONSIDERING TRIAL DESIGN TO ENABLE DATA CAPTURE

| Rave eCOA

CHALLENGE	SOLUTION
Provide ways for missed or risked visit forms to be remotely lled out by patients on existing studies.	Medidata's eCOA solution can be used to convert site-based data forms to remote data forms. If study modi cations are made to accommodate this approach, patients can download the patient cloud app from the app store and provide urgent data forms as needed for missed visits. Any Rave EDC study using eCOA can have additional data forms pulled into the eCOA app and made available to patients. Any Rave EDC studies not using eCOA can add eCOA to the project and immediately begin converting forms to remote-enabled forms.

CHALLENGE

SOLUTION

In late April, Medidata an... ...ptom Tracker* as part of **myMedidata***

CHALLENGE 3: MAINTAINING QUALITY AND SUPPLY

CHALLENGE

...nt
...on
...ing
...ed o
...es wit
...ted
...ns,
...onsite
...ll
...he number
...lowed

...and CROs must
...the current risks
...and data integrity
...act to the site as

...ew Medidata Solution

Restrictions of access to sites by staff and patients may affect the investigators' ability to maintain medical oversight. This may impact, among other key processes,

SOLUTION

The industry has traditionally re... monitoring including signi cant amounts of Source Data Review (SDV) to ensure subject safety and generate quality data. This approach is highly resource intensive, costly, and has been found to have minimal impact on the quality of the clinical investigation when compared to less resource-intensive approaches.

It's well supported that 100% SDV has a negligible effect on data quality. A reduced SDV methodology has been increasingly encouraged by TransCelerate & global regulatory authorities. Applying a risk-based approach to reduced SDV enables sponsors and CROs to quickly navigate monitoring backlog resulting in earlier indications of potential subject safety, data quality issues, and study risks.

Medidata has enabled **targeted source data veri cation** through a new COVID-19 focused offering, **TSDV Critical***, to support sponsors and CROs in delivering quality data in a time effective and cost ef cient method:
• Regulatory supported method for identifying critical data to perform reduced SDV
• Targeted critical data to focus attention
• Fully auditable solution
• Elimination of manual CRA determination of monitoring requirements
• Real-time reporting capabilities for sponsor and CRO oversight responsibilities
• Cost effective method for reduction in labor intensive onsite monitoring activities

Medidata offers consulting services to support to support a streamlined implementation process :
• COVID-19-speci c Risk Management
• Streamlined Block/Tier plan based on study risk
• TSDV best practices guide
• Sample text for inclusion with monitoring (functional) plan for:
    • Supporting a reduced SDV approach
    • Guidance on training for monitors

CHALLENGE

SOLUTION

Rave CSA Critic... ...ution to support sponsor oversight ...analytical tools and algorithms into a quic... ...) providing:

- Real-time data availability for ... oversight
- Focused Key Risk Indicators (KRI) on areas of greatest risk
- Remote management of site processes to mitigate risk
- Detection of data patterns and anomalies
- Automated insights into subject safety, data integrity, and site performance
- Mitigation of risk due to site monitoring and patient visit disruption

These allow for increased efﬁciency in data review and centralization of review activities and risk/issue detection - a critical capability that can maintain and support sponsor oversight responsibilities and allow earlier access to data and enhance key decisions making capabilities.

CHALLENGE

...obal restrictions, ...s are experiencing ...o adequately monitor ...studies on site, and ...e able to manage critical ...t acquisition and SDR ...es. .Some have turned to ...ecure, antiquated, risky ...s to manage these critical ...cuments such as fax, email, ...ideo and ﬁle sharing software ...Without the ability to securely **manage these documents, patient safety and data integrity are at risk and studies may not progress.**

Regulatory guidance allows for sponsors to ﬁnd ways to perform critical document management and SDR remotely via a secure cloud-based viewing portal in certain regions, excluding EMEA.

*New Medidata Solution

SOLUTION

Based on the current FDA Guidance, Medidata has tailored its Rave imaging workﬂow tool to enable clients to rapidly and remotely deploy a method to assist monitors in their critical document acquisition, tﬂworkﬂow, and Source Document Review (SDR). **Rave Imaging Critical*** is a streamlined and quick-to-implement solution (2 weeks go-live) that helps ﬁll the gap when studies have critical timelines and no secure option to collect, de-identify, manage, review and verify critical study documents. Easy to get started with no software to download, is available at no cost to the sites, and can be used as a primary solution or alternative for sites.

Rave Imaging Critical:
- Acquires documents, via secure browser-based uploads, routes and manages document workﬂows to support source document review and veriﬁcation remotely
- Is a 21 CFR Part 11 compliant system that includes the ability to de-identify and redact Personally Identiﬁable Information (PII) and Protected Health Information (PHI)
- Mitigates risk due to site monitoring and patient visit disruption for some studies with no secure option to manage critical documents

CHALLENGE

SOLUTION

Sites can process disp_____send the drug to the subject via a courier. Rave EDC co_____tracking number (collected as text data). Adding a new eld would _____Rave EDC.

There are several options to have drug sent to the patient from the depot or a central pharmacy. In Rave RTSM (randomization and trial supply management), the subject has to exist at the site where the drug supply is located. There are several options we are executing to manage transferring subjects and creating dummy shipments to allow a shipment to be sent to the patient's home from a location other than the site. We're able to work with study teams to help set up the best option based on the study design and logistic considerations.

Some of the methods above can also be used to allow a direct to patient shipment when the site is closed. Alternately, subjects may be transferred to sites that are open. We have a "How-to" procedure ready to share with you.

Multiple dispensing visits can be made in Rave EDC at the same time, providing additional IMP for the subject. If this will become standard, DND dates should be updated so that the drug does not expire over the longer time period between dispensations. Our Services team can provide speci c steps that can be utilized to ensure off-cycle/unscheduled visits can be conducted without issue.

Supply plans can be instantly adjusted by end users to meet the changing needs of individual study sites. To ensure that the site is stocked with additional drug to service a larger number of visits, the maximum buffer can be increased or the long window extended. Alternatively, a supply plan can also be adjusted to maintain less inventory by shortening the long window or reducing the maximum buffer. The site can also be deactivated for shipping in the case of a closed site or dispensations occurring from alternate sites.

CHALLENGE 4: ACCELERATING STUDY START-UP

CHALLENGE

SOLUTION

...-19 pandemic, we find ou... ...months of lockdown, ...d municipalities begin to ... ...e keeping a watchful eye ...e countries are reopening while t... ...s to rise; others are moving with ...including South Korea, Lebanon and Germany... ...introducing lockdowns, after attempts to ...ks. ...e U.S. is a patchwork, with widely different reactions and responses across the country.

...y complex picture makes it even more vital that we at Medidata continue to monitor clinical trial ...site, and provide up-to-date information to our customers and partners. Time – and data – will ...relax quarantines will impact drug development and discovery.

...roviding this data to our stakeholders, along with relevant updates from a regulatory perspective.