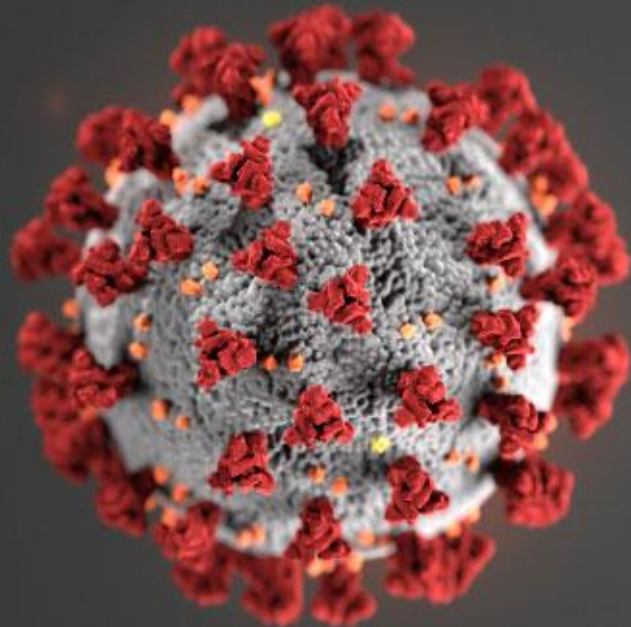


SARS-Cov-2 Report

José Luis Pires

29 May 2020



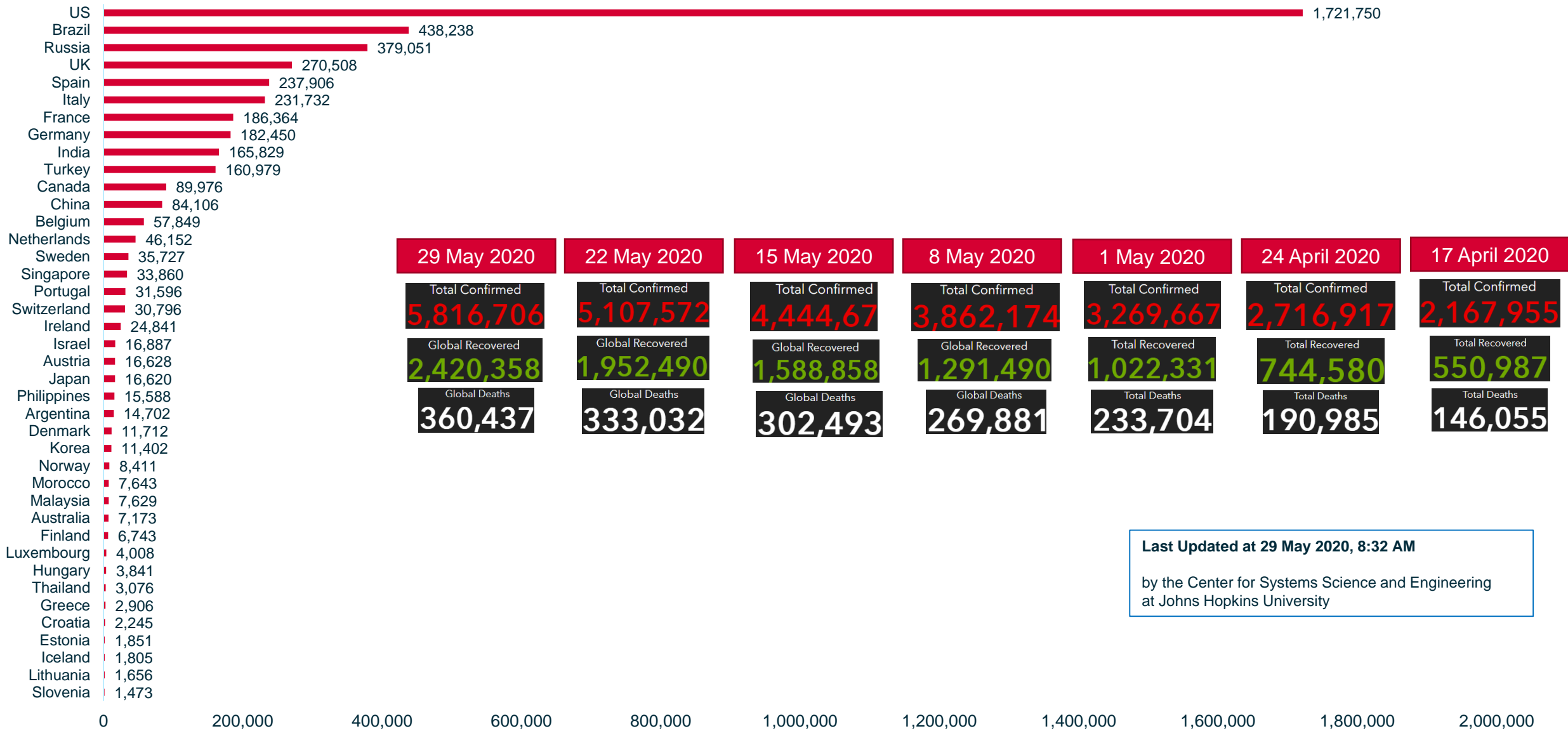
Contents

SARS-Cov-2

- Confirmed cases by Country
- Deaths by Country
- Total confirmed Covid-19 cases and deaths per million people
- Portugal, Loures, Macau, New Jersey, Ireland - Cases by day and Total
- Reported infections per 1 million people for select countries with over 100 reported cases
- New cases vs 7-day average
- Cases Curve Simulator
- The latest coronavirus updates and developments impacting the global pharmaceutical supply chain

Coronavirus (SARS-CoV-2 / Covid-19) – Confirmed cases by country

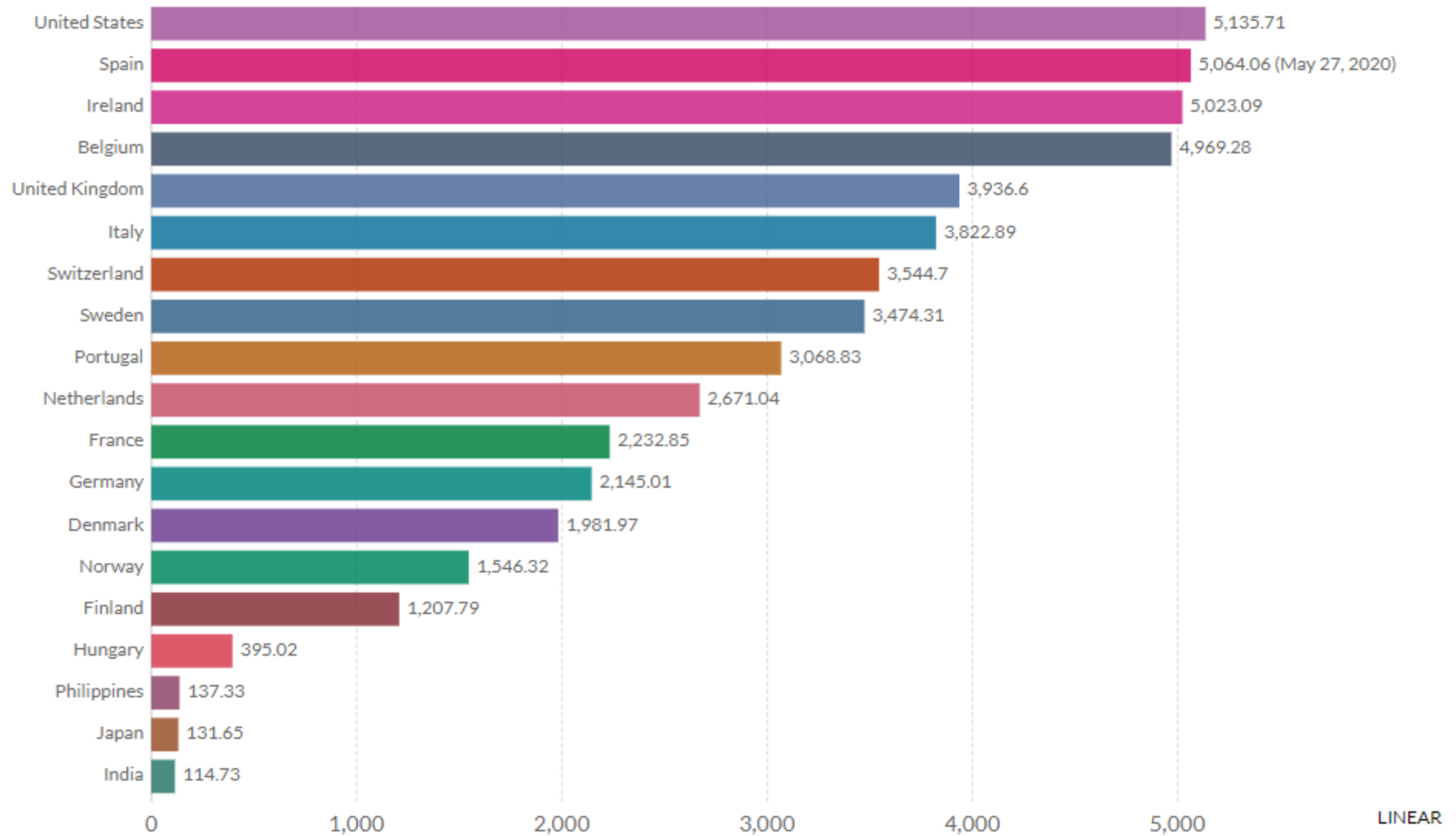
Note: Selected Countries, sorted by # of cases



Last Updated at 29 May 2020, 8:32 AM
 by the Center for Systems Science and Engineering
 at Johns Hopkins University

Source: <https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>

Total confirmed Covid-19 cases per million people

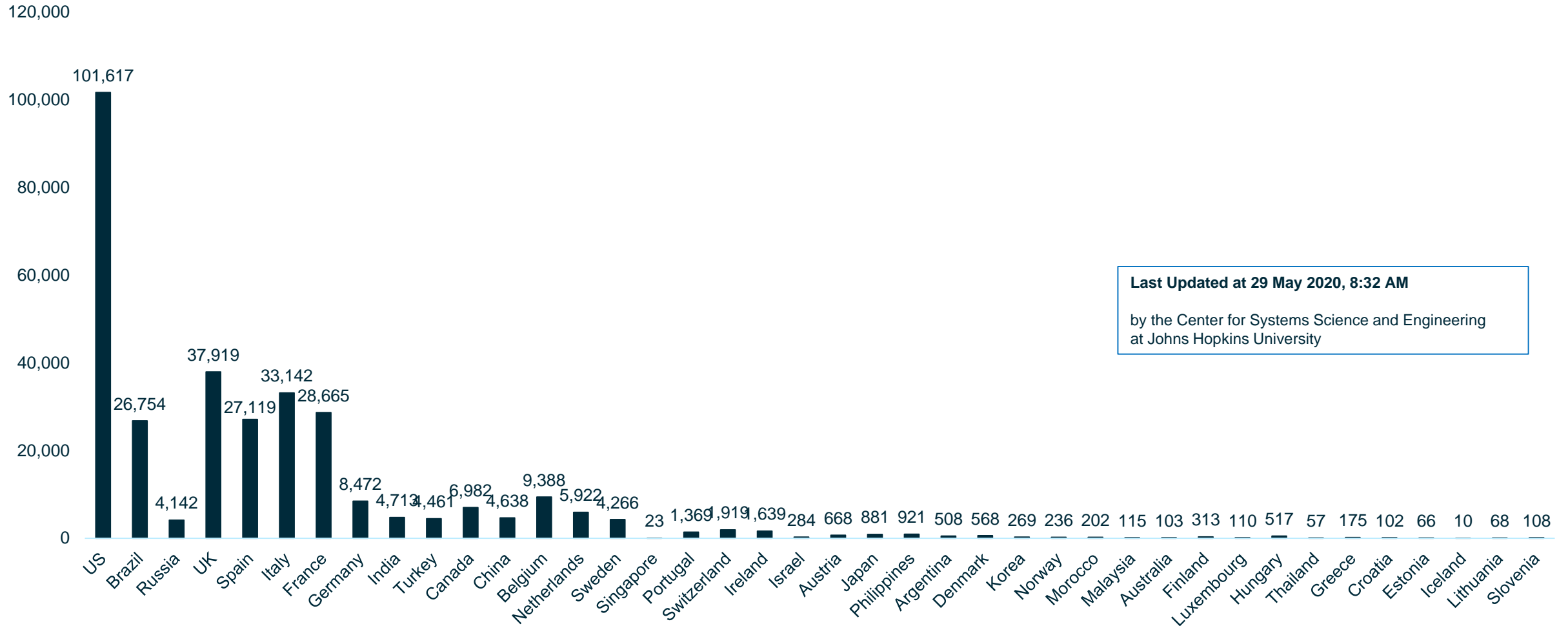


Source: European CDC - Situation Update Worldwide - Data last updated 28th May, 21:57 (GMT+01:00)

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Coronavirus (SARS-CoV-2 / Covid-19) – Deaths by Country

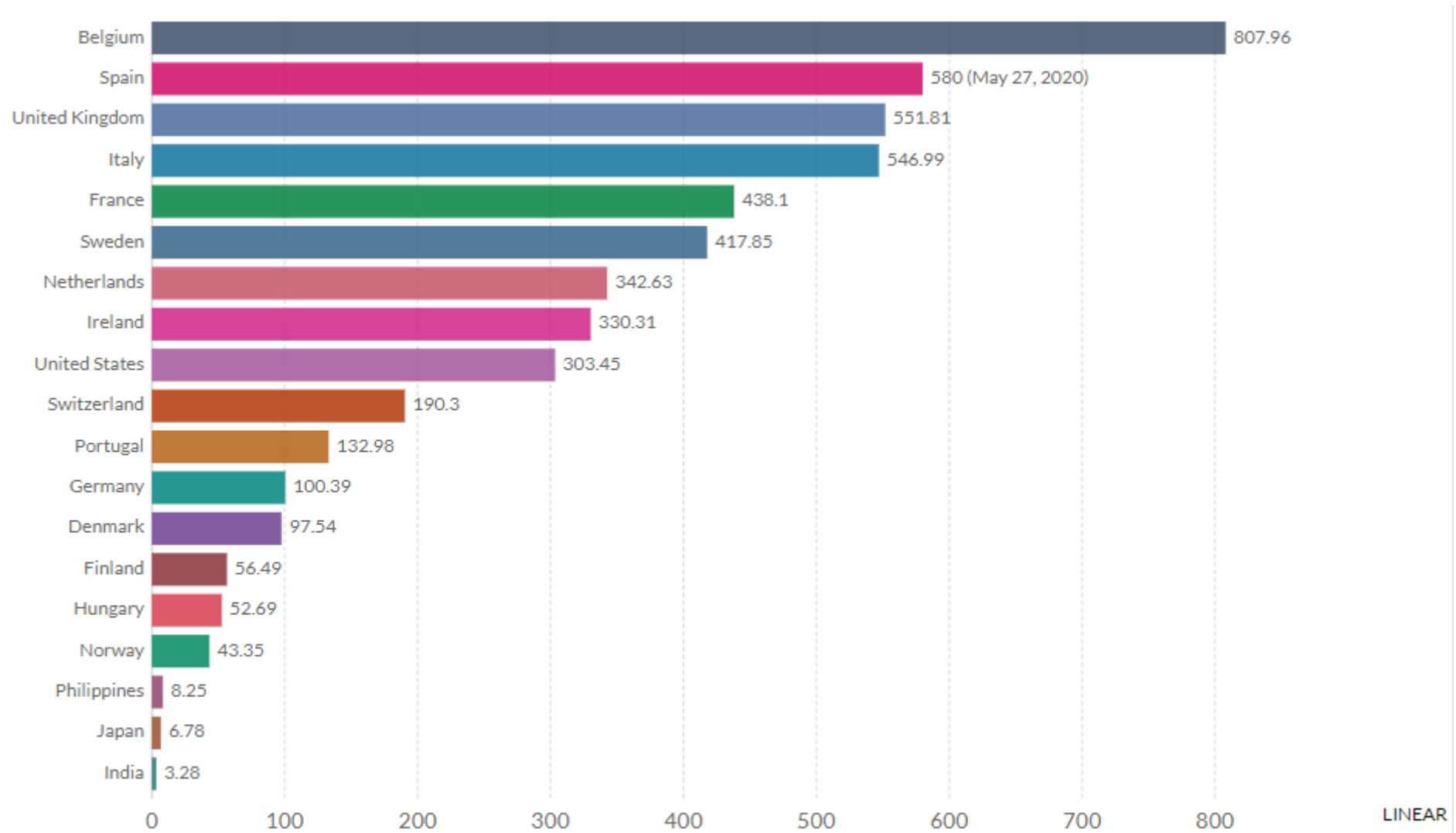
Note: Selected Countries, sorted by # of cases



Last Updated at 29 May 2020, 8:32 AM
 by the Center for Systems Science and Engineering
 at Johns Hopkins University

Source: <https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>

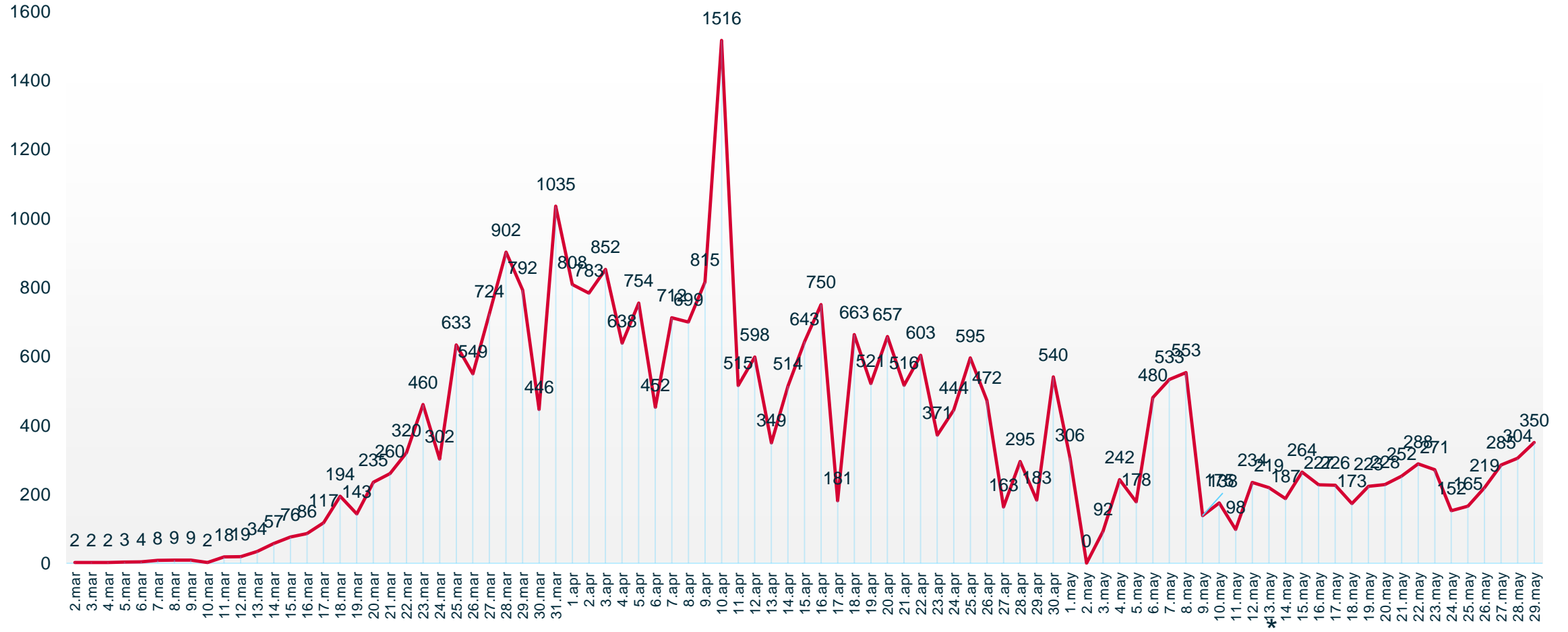
Total confirmed Covid-19 deaths per million people



Source: European CDC - Situation Update Worldwide - Data last updated 28th May, 21:57 (GMT+01:00)

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Coronavirus (SARS-CoV-2 / COVID 19) – Portugal - Confirmed cases by day

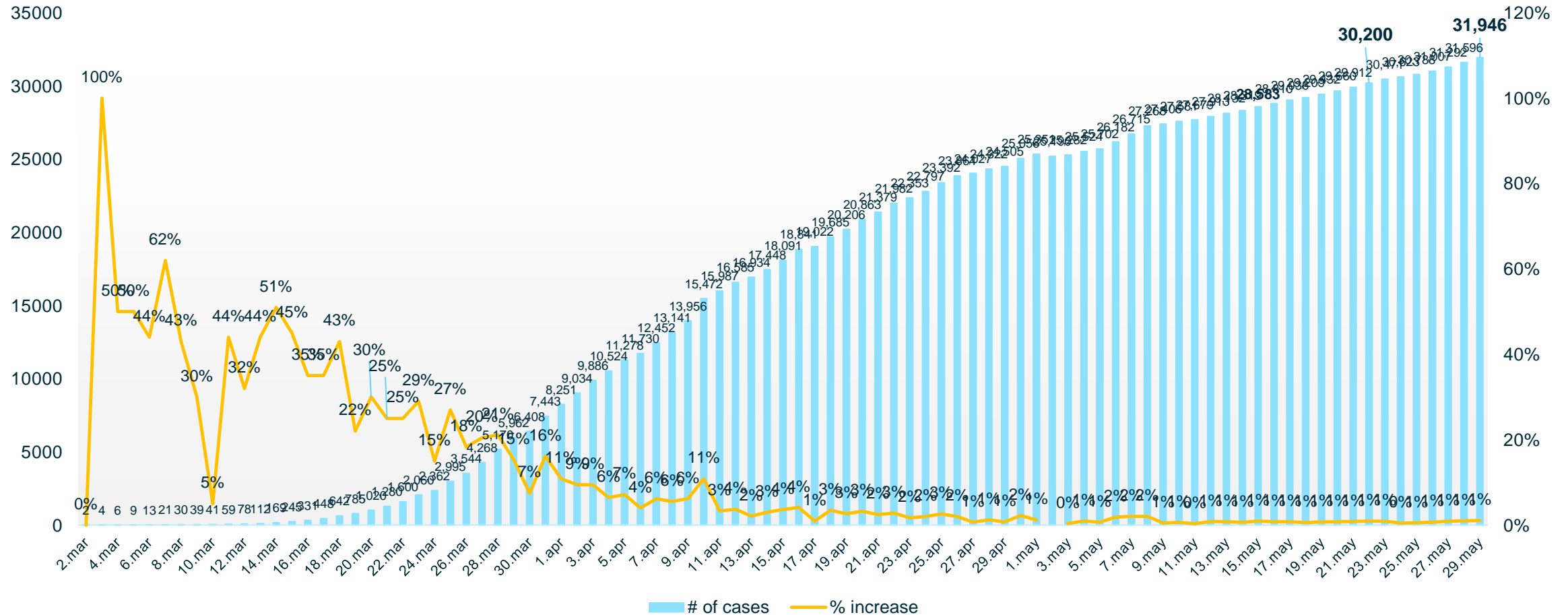


Source: <https://covid19.min-saude.pt/ponto-de-situacao-atual-em-portugal/>

* - recalculated numbers



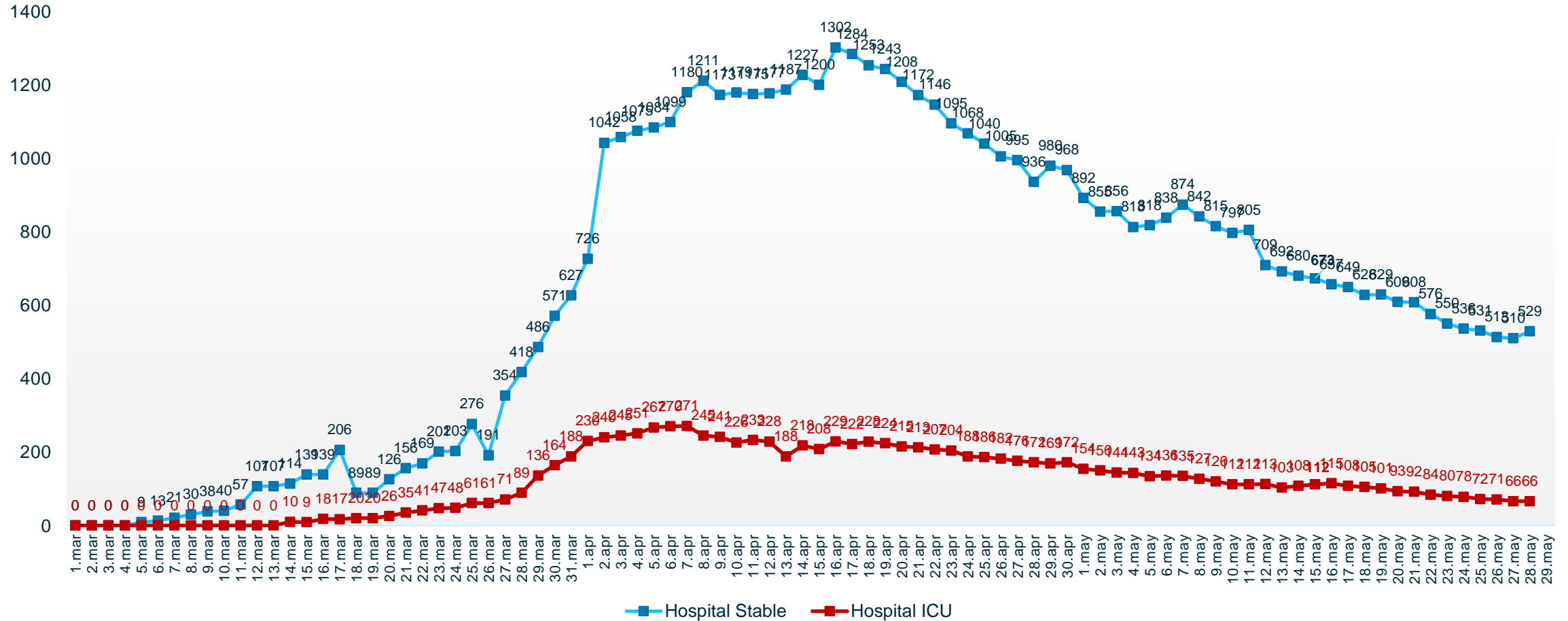
Coronavirus (SARS-CoV-2 / COVID 19) – Portugal - Total cases by day



Source: <https://covid19.min-saude.pt/ponto-de-situacao-atual-em-portugal/>



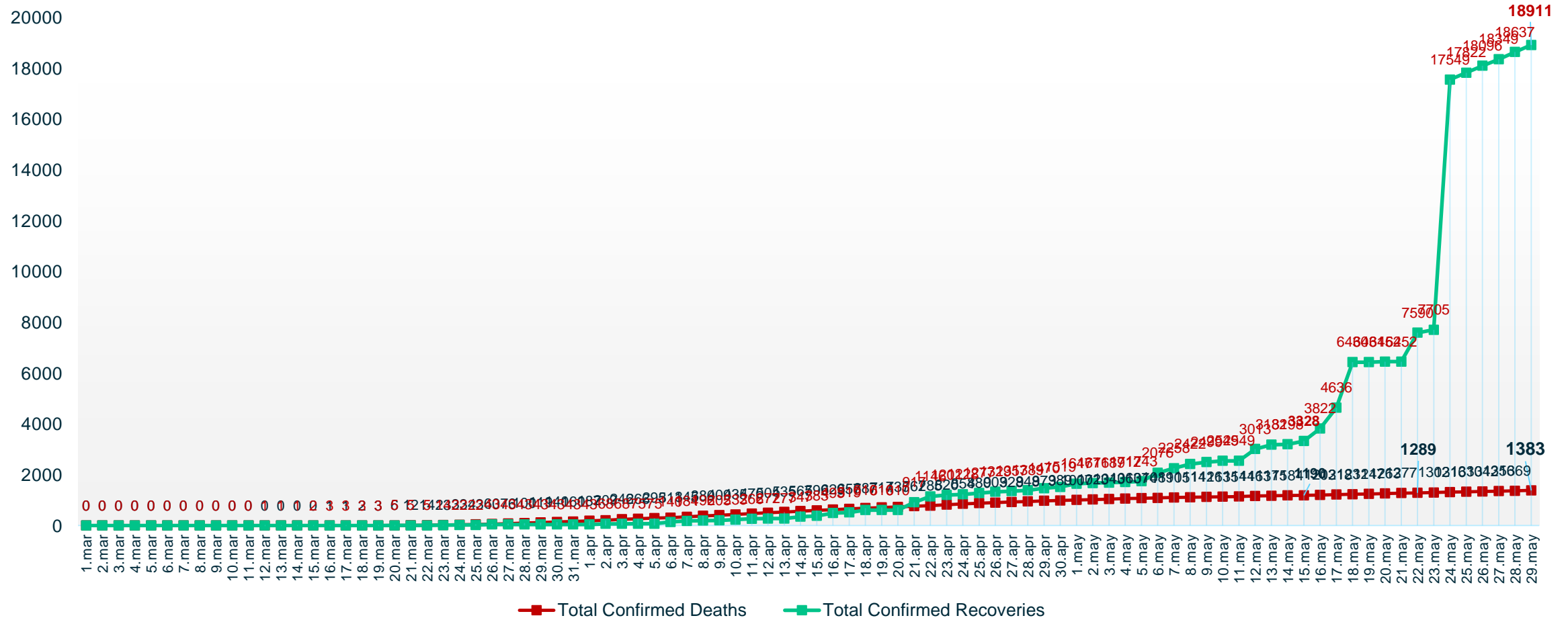
Coronavirus (SARS-CoV-2 / COVID 19) – Portugal – Hospital: Stable vs ICU



Source: <https://covid19.min-saude.pt/ponto-de-situacao-atual-em-portugal/>



Coronavirus (SARS-CoV-2 / COVID 19) – Portugal – Deaths vs Recoveries

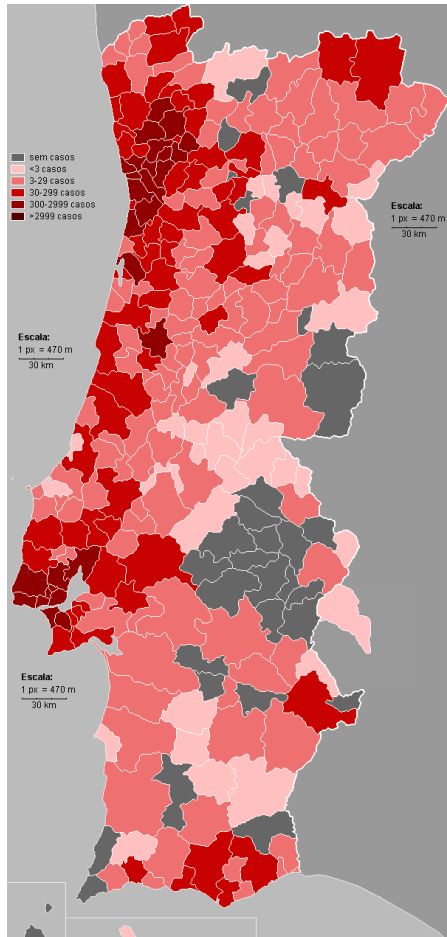


Source: <https://covid19.min-saude.pt/ponto-de-situacao-atual-em-portugal/>



Coronavirus (SARS-CoV-2 / COVID 19) – Portugal – 28 May 2020

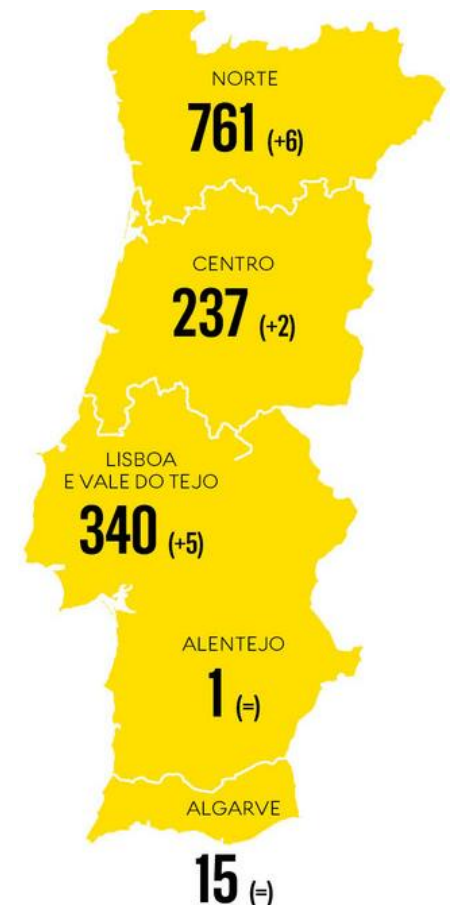
Confirmed Cases



Confirmed Cases - Total



Deaths - Total

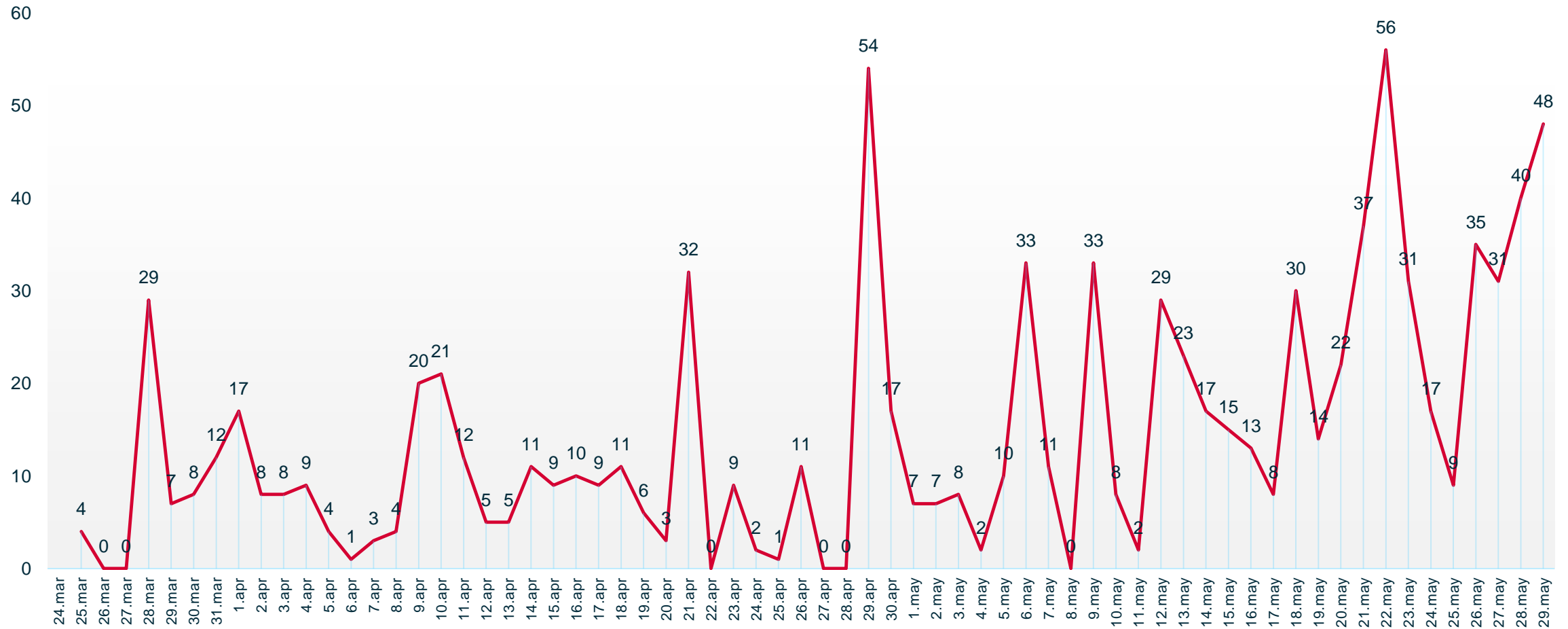


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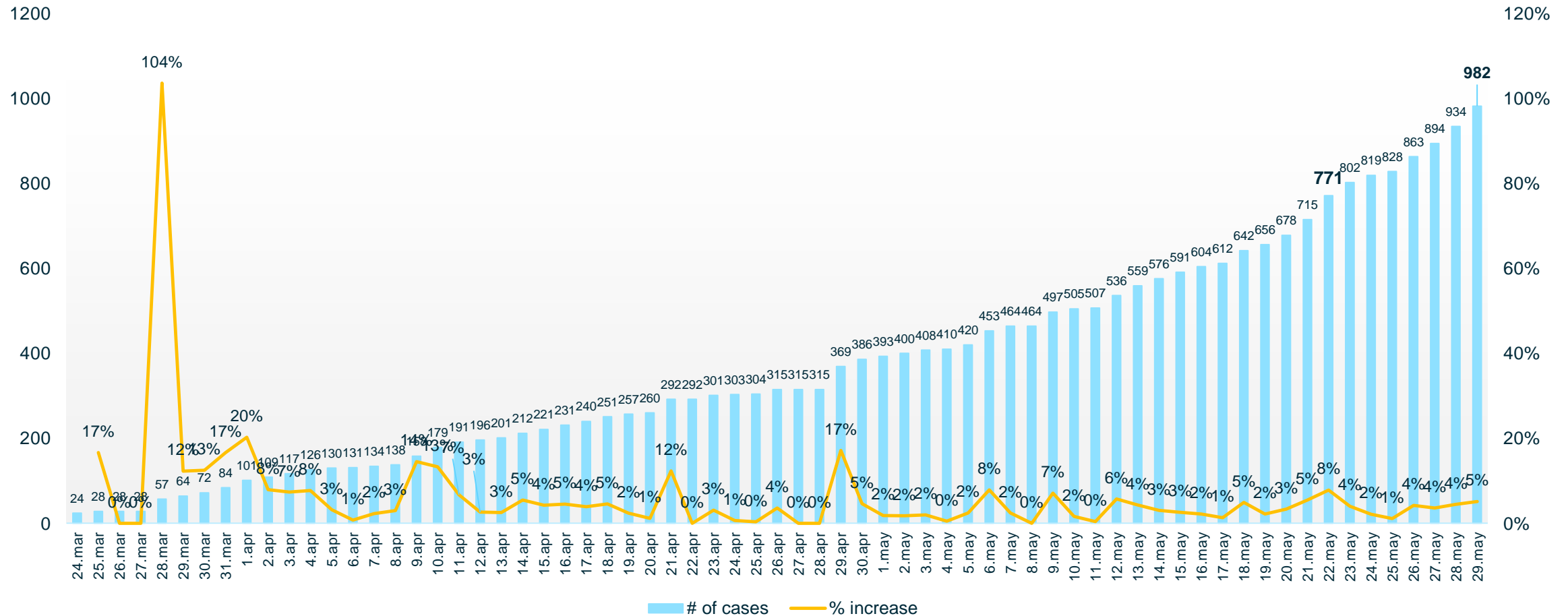
-05-15-Covid-19.-O-maior-aumento-de-novos-casos-ous-um-novo-sete-dias-o-situ-em-Portugal--em-graficos-e-mapas-

Coronavirus (SARS-CoV-2 / COVID 19) – Loures - Confirmed cases by day



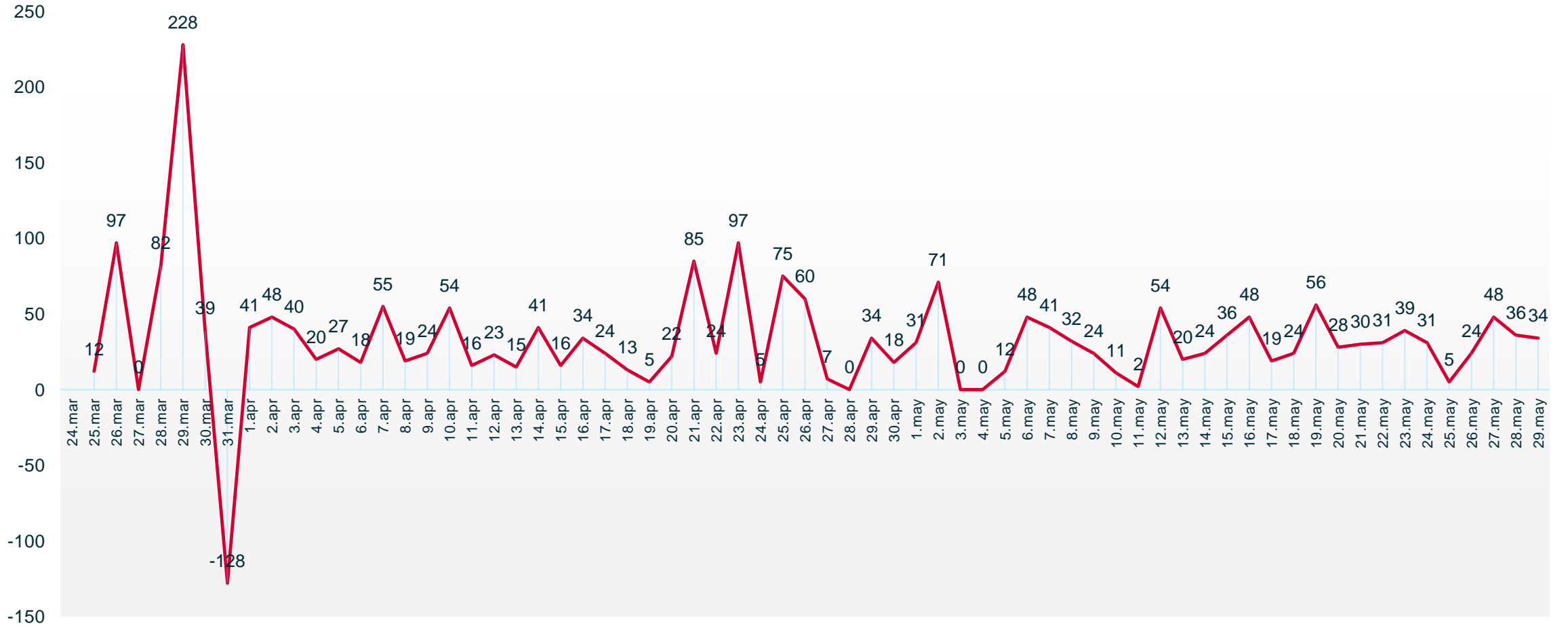
Source: <https://covid19.min-saude.pt/ponto-de-situacao-atual-em-portugal/>

Coronavirus (SARS-CoV-2 / COVID 19) – Loures - Total cases by day



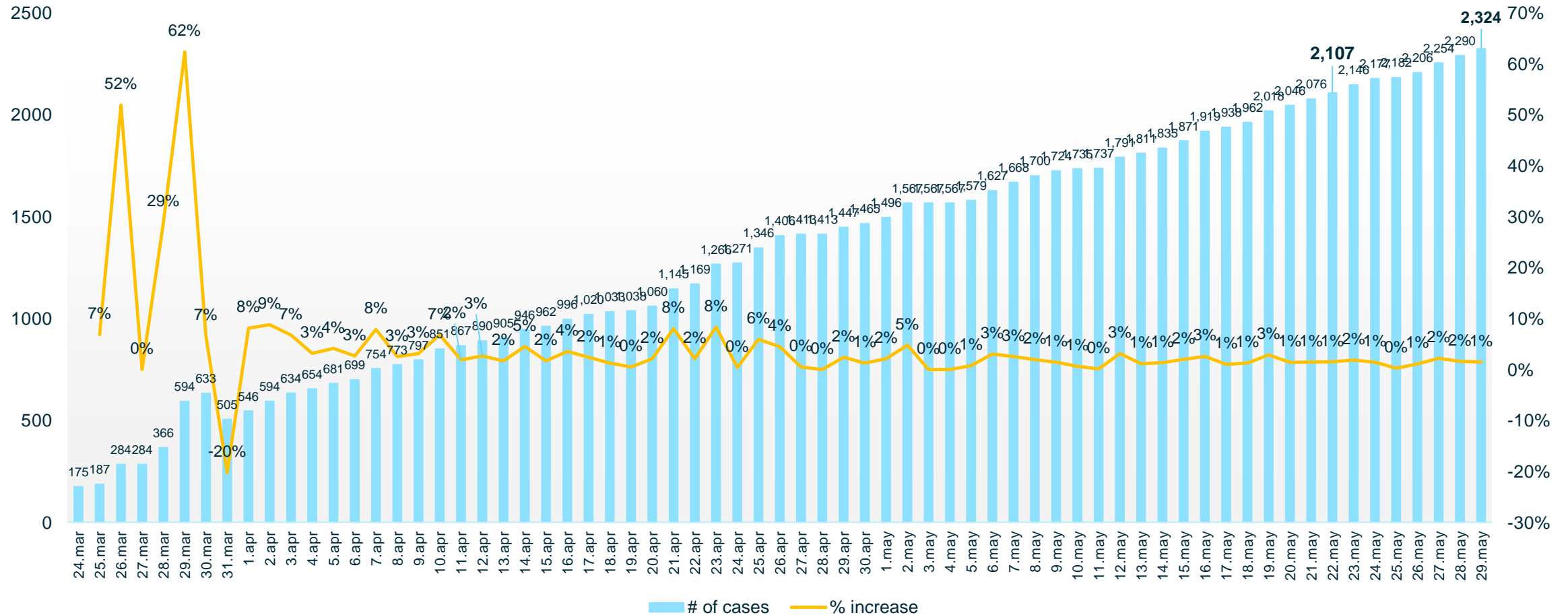
Source: <https://covid19.min-saude.pt/ponto-de-situacao-atual-em-portugal/>

Coronavirus (SARS-CoV-2 / COVID 19) – Lisbon - Confirmed cases by day



Source: <https://covid19.min-saude.pt/ponto-de-situacao-atual-em-portugal/>

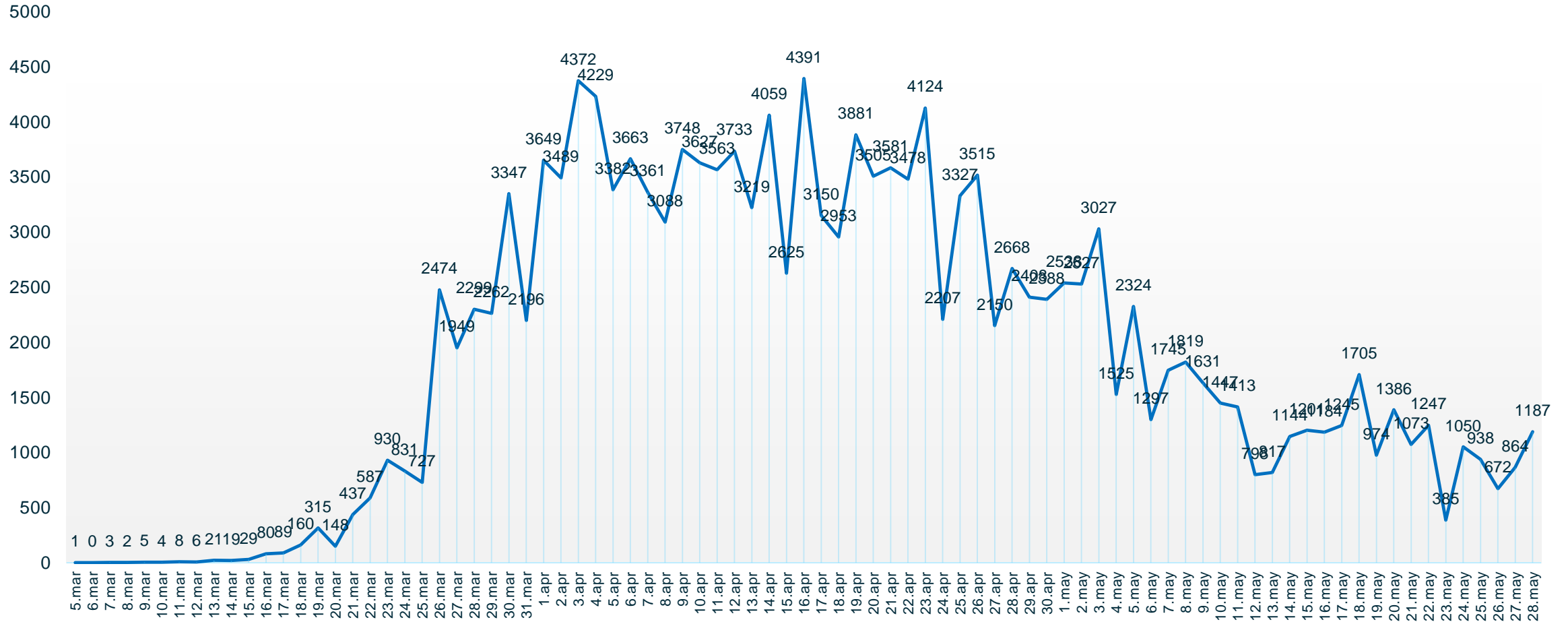
Coronavirus (SARS-CoV-2 / COVID 19) – Lisbon - Total cases by day



Source: <https://covid19.min-saude.pt/ponto-de-situacao-atual-em-portugal/>

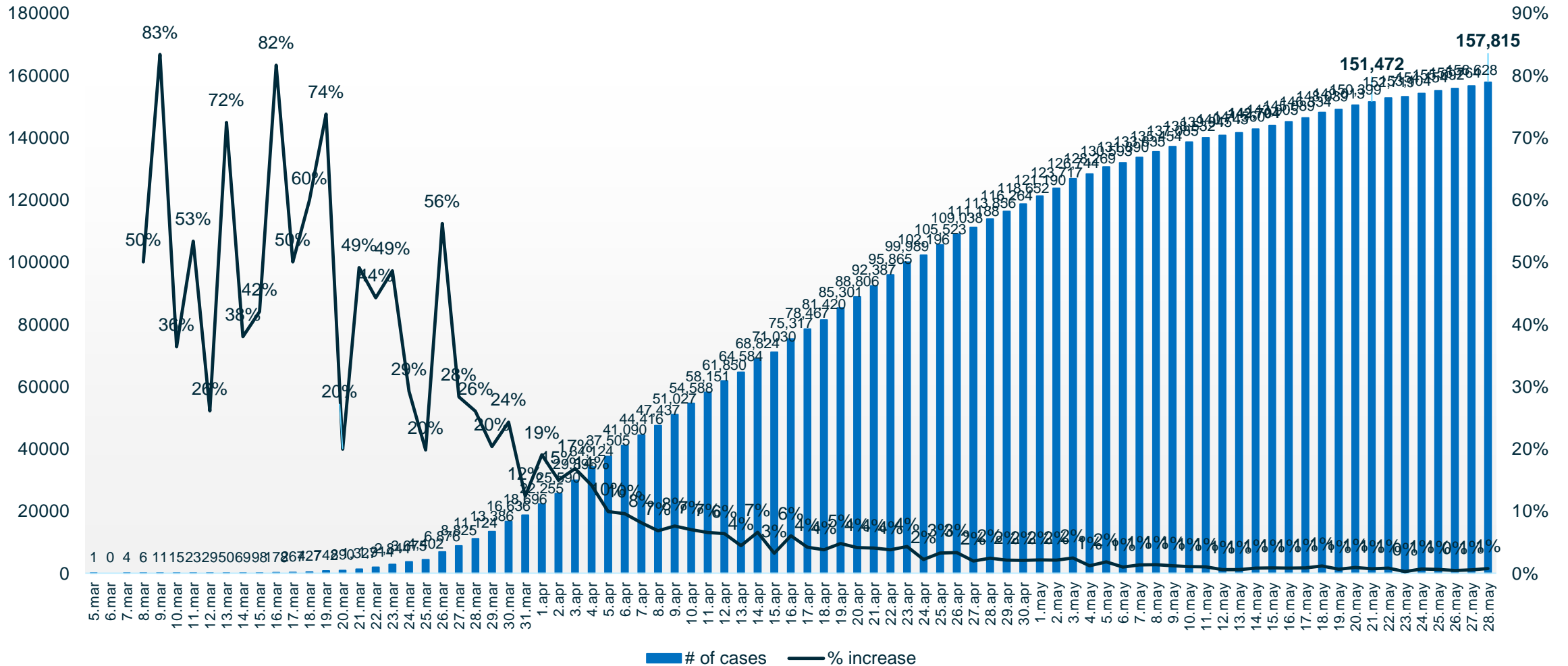


Coronavirus (SARS-CoV-2 / COVID 19) – **New Jersey** - Confirmed cases by day



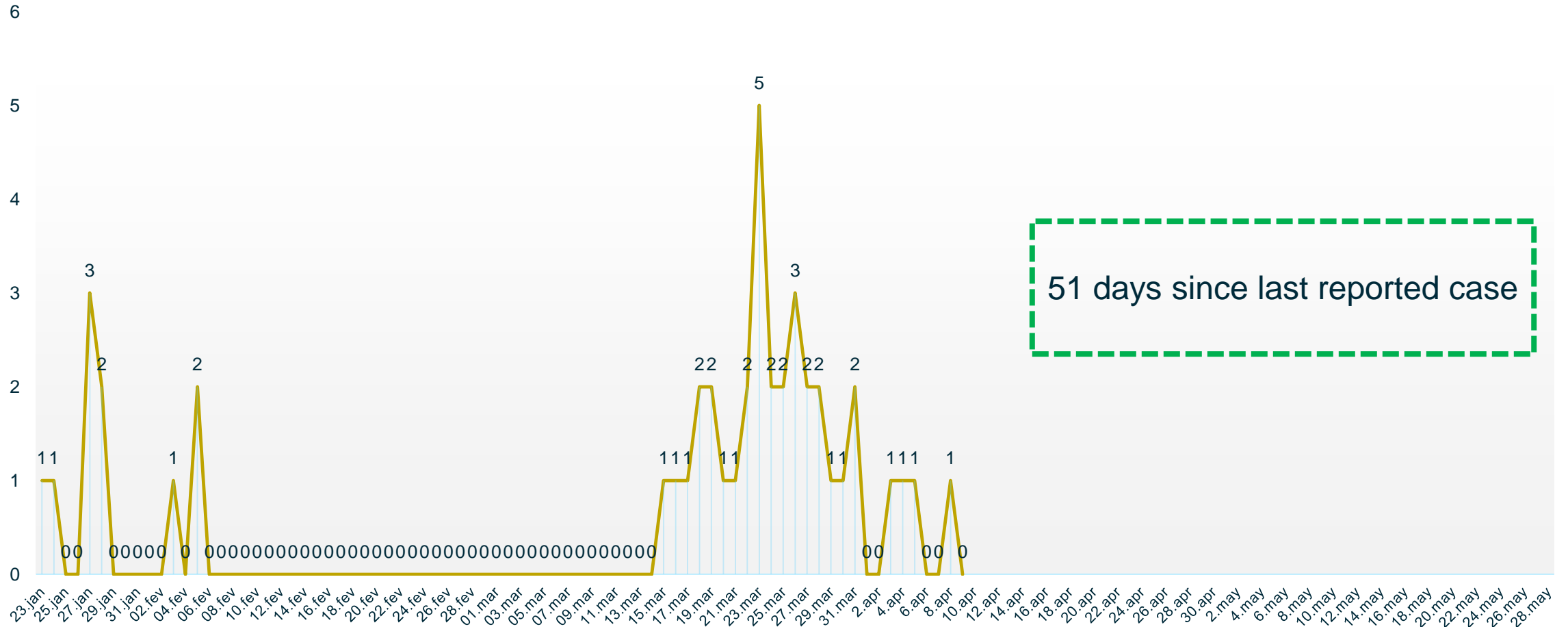
Source: <https://www.nj.com/coronavirus/2020/03/see-the-spread-of-nj-coronavirus-in-charts-map-sunday-march-22-2020.html>

Coronavirus (SARS-CoV-2 / COVID 19) – New Jersey - Total cases by day



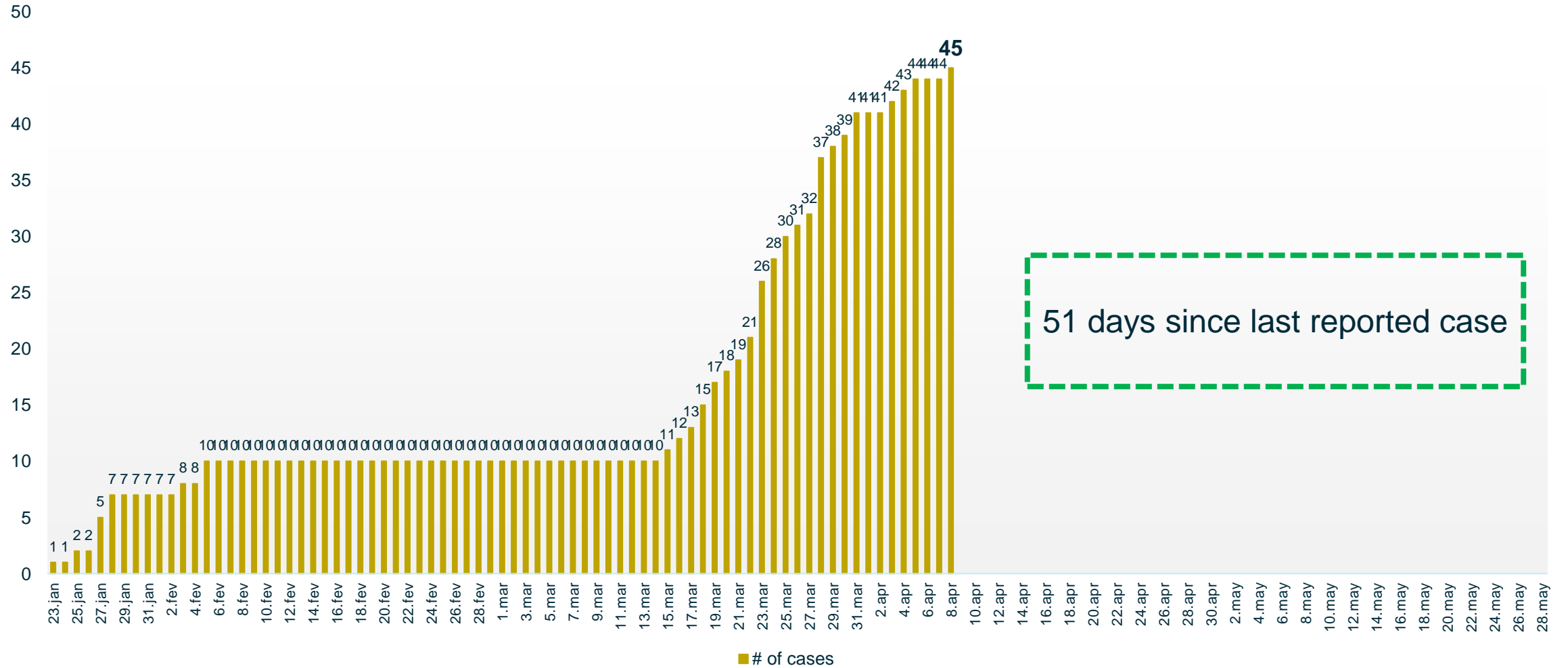
Source: <https://www.nj.com/coronavirus/2020/03/see-the-spread-of-nj-coronavirus-in-charts-map-sunday-march-22-2020.html>

Coronavirus (SARS-CoV-2 / COVID 19) – Macau - Confirmed cases by day



Source: <https://www.ssm.gov.mo/Portal/portal.aspx?lang=pt>

Coronavirus (SARS-CoV-2 / COVID 19) – Macau - Total cases by day



51 days since last reported case

Source: <https://www.ssm.gov.mo/Portal/portal.aspx?lang=pt>



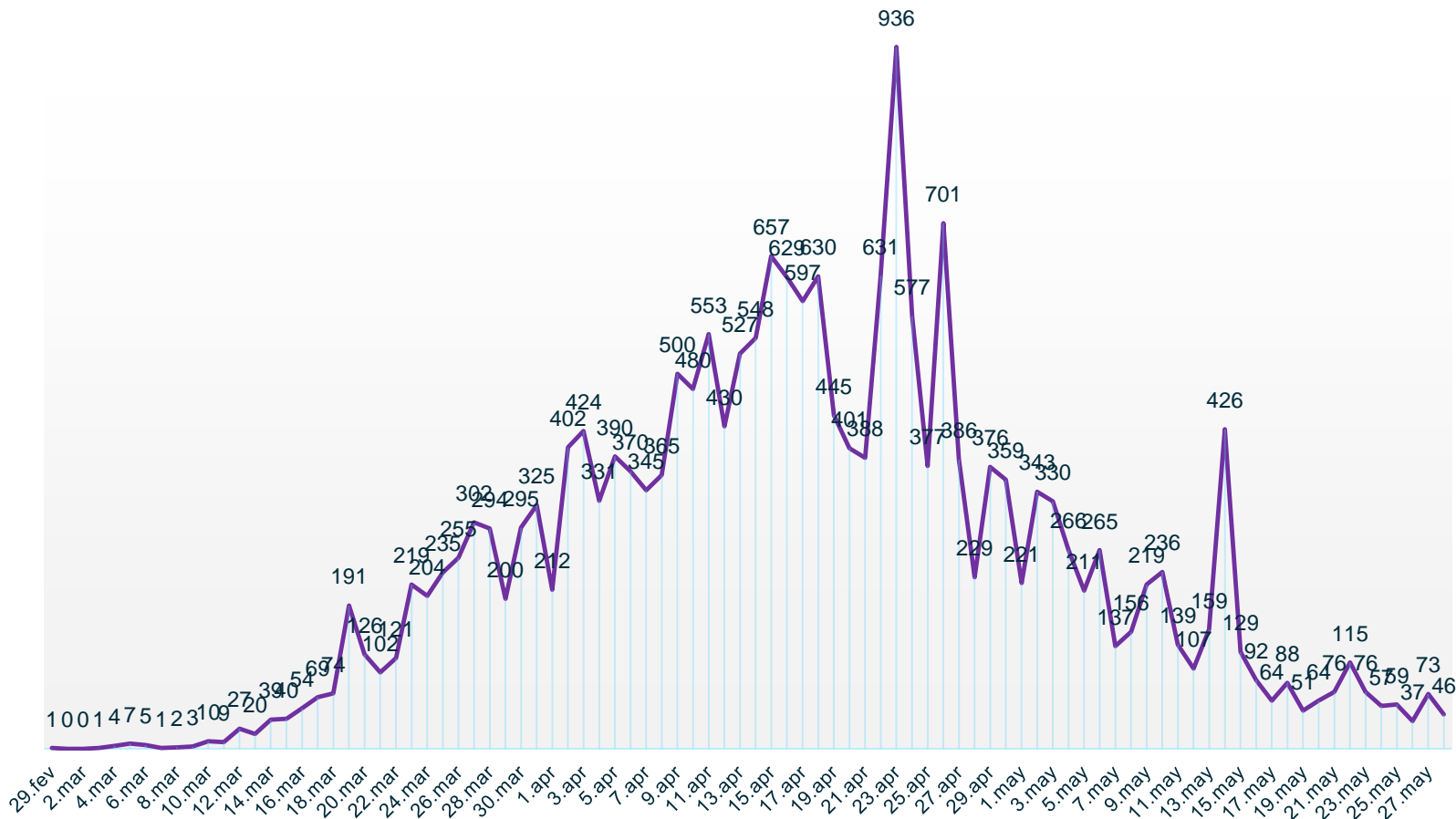
May 2020

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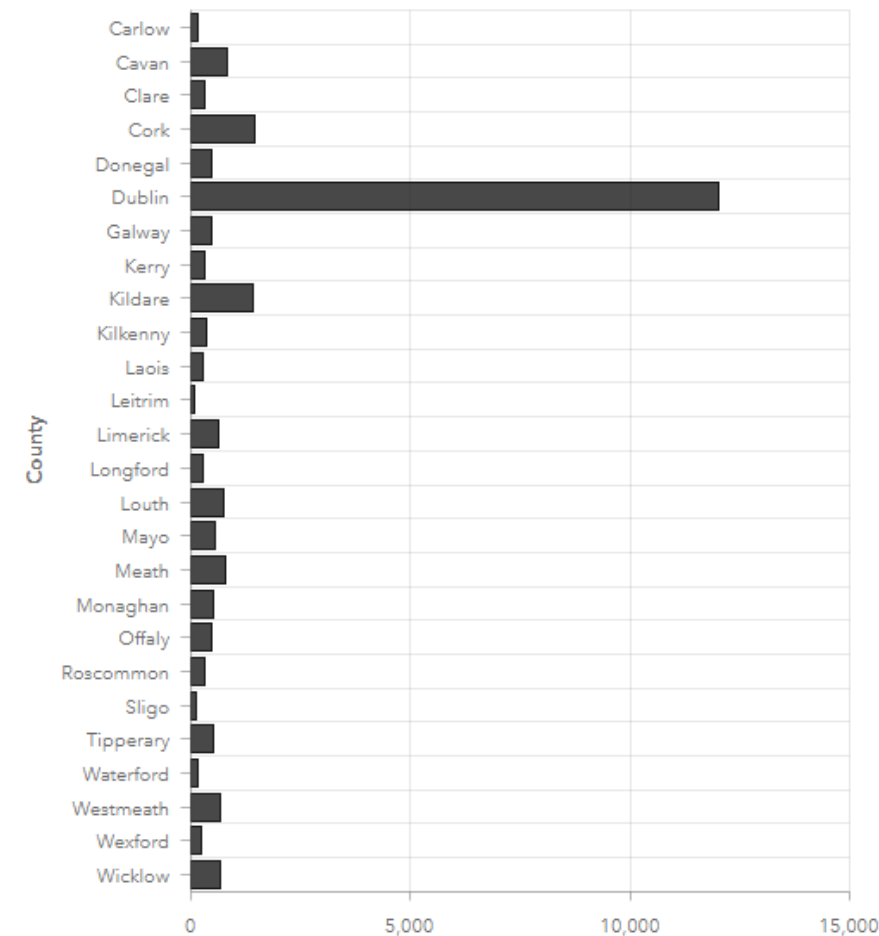
19

In it for life

Coronavirus (SARS-CoV-2 / COVID 19) – Ireland - Confirmed cases by day

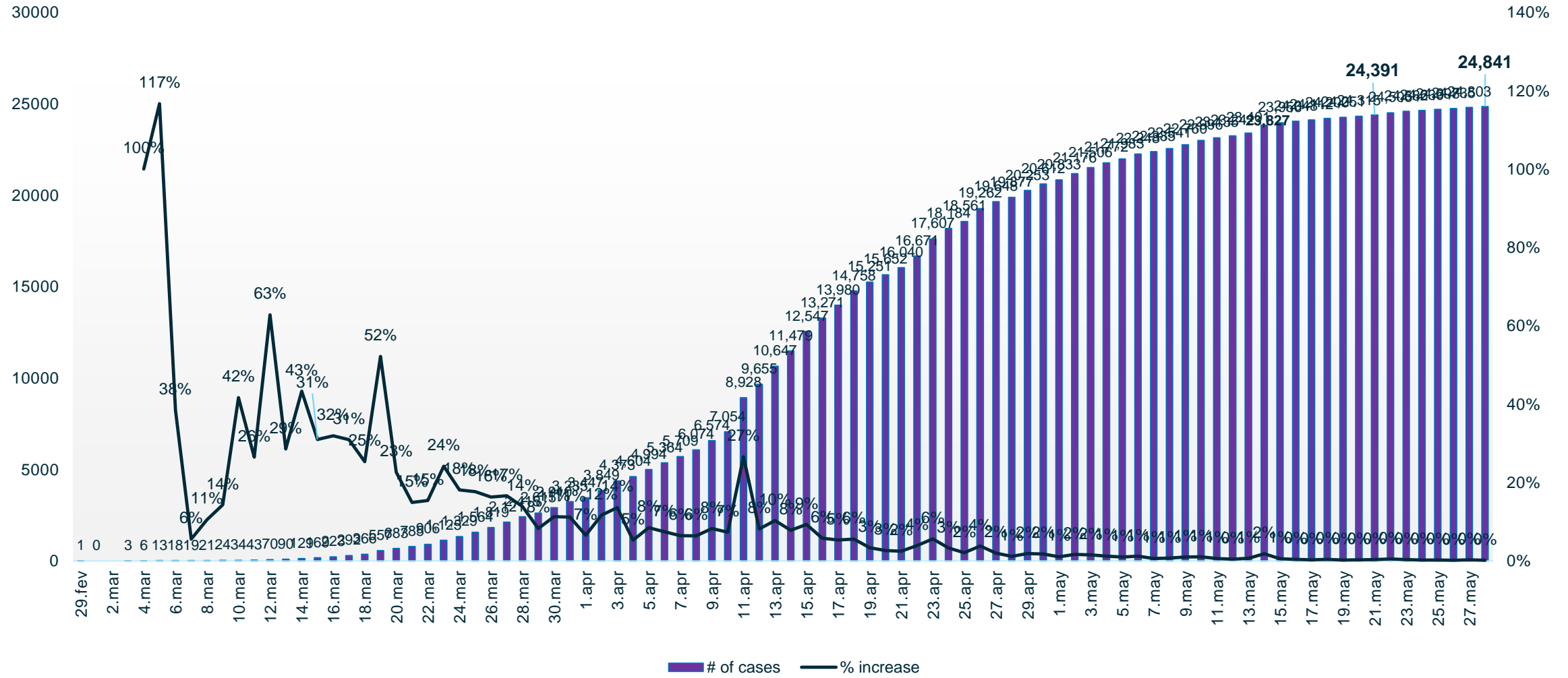


Total Confirmed Cases by County (26/05/2020)
To see more results, hover over the top right of this chart and click the expand icon.



Source: <https://geohive.maps.arcgis.com/apps/opsdashboard/index.html#/29dc1fec79164c179d18d8e53df82e96>

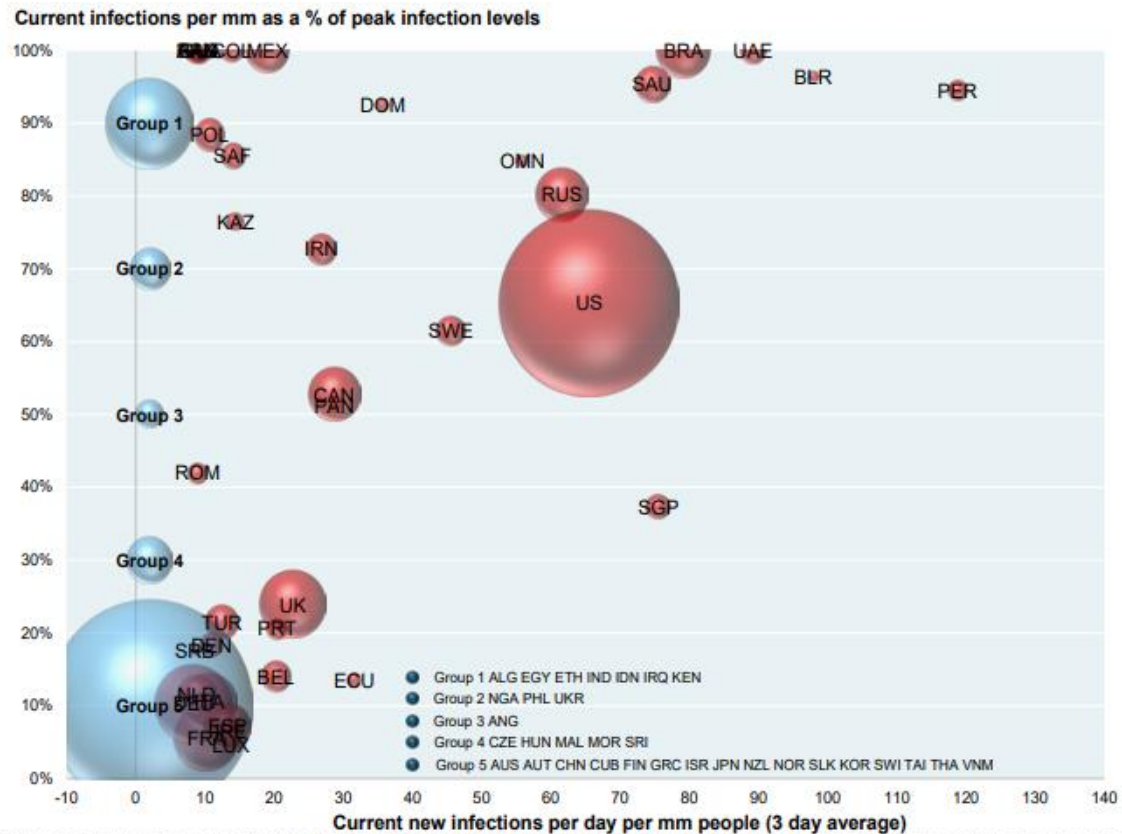
Coronavirus (SARS-CoV-2 / COVID 19) – Ireland - Total cases by day



Source: <https://geohive.maps.arcgis.com/apps/opsdashboard/index.html#/29dc1fec79164c179d18d8e53df82e96>

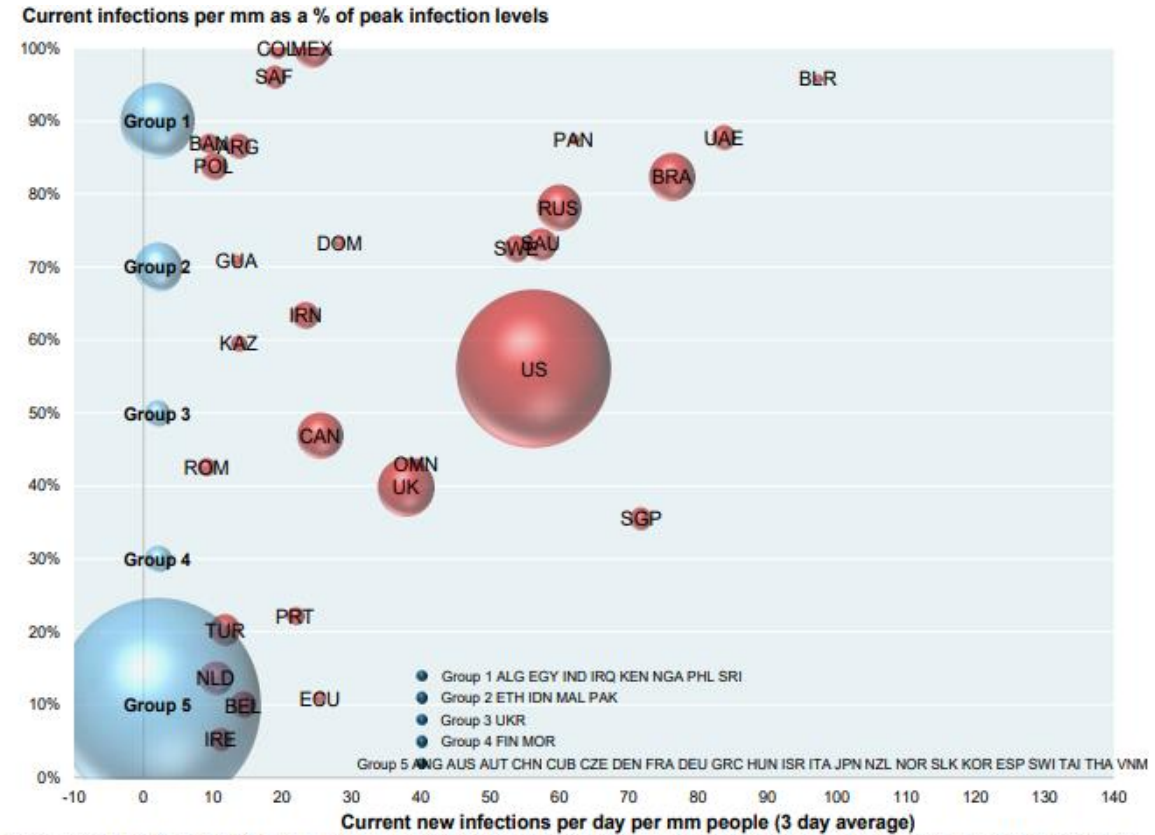
Global infection snapshot: latest infection trends, declines from peak infection levels and country GDP (size of bubble)

May 20, 2020



Source: Johns Hopkins University, IMF, JPMAM. May 20, 2020. Countries with current infections per day below 8 people per mm are aggregated into 5 groups according to decline rate.

May 27, 2020

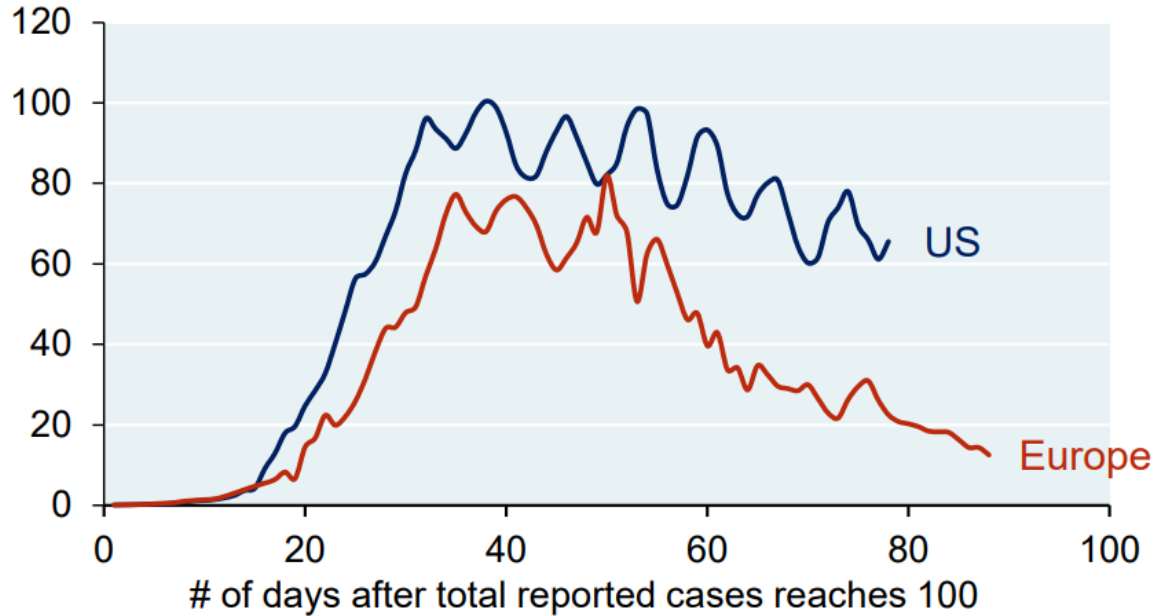


Source: Johns Hopkins University, IMF, JPMAM. May 27, 2020. Countries with current infections per day below 8 people per mm are aggregated into 5 groups according to decline rate.

New daily infections per 1 million people

May 20, 2020

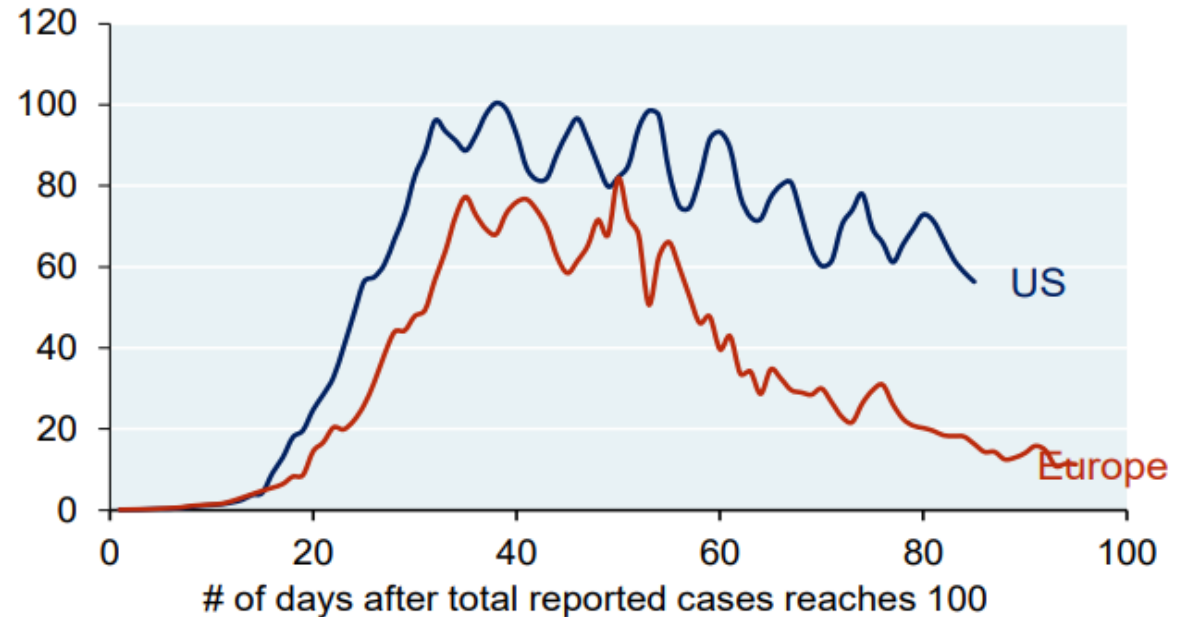
New daily infections per mm people
Linear scale, 3 day trailing average



Source: Johns Hopkins University, IMF, JPMAM. May 20, 2020

May 27, 2020

New daily infections per mm people
Linear scale, 3 day trailing average

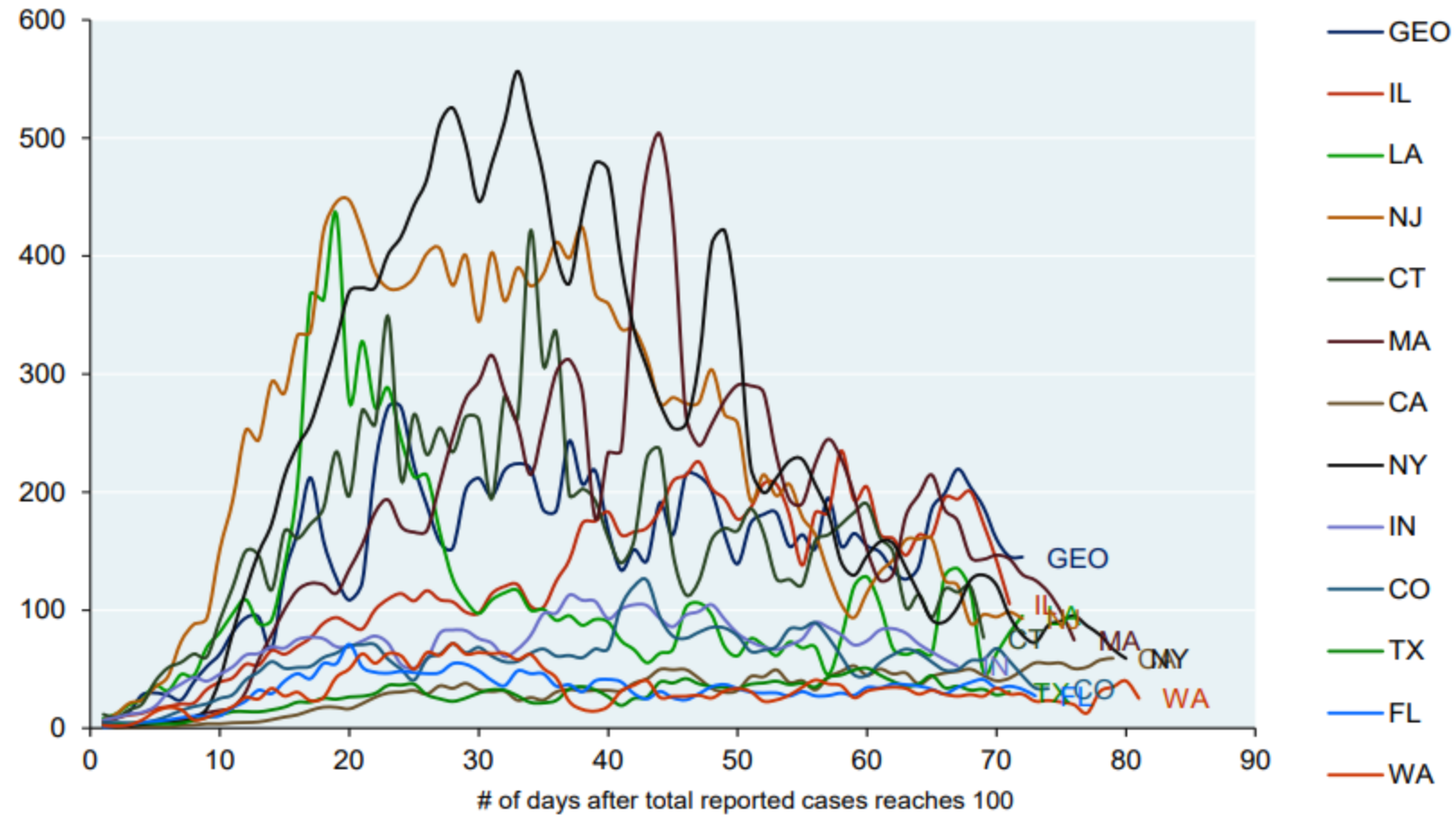


Source: Johns Hopkins University, IMF, JPMAM. May 27, 2020

Infection and mortality for US states

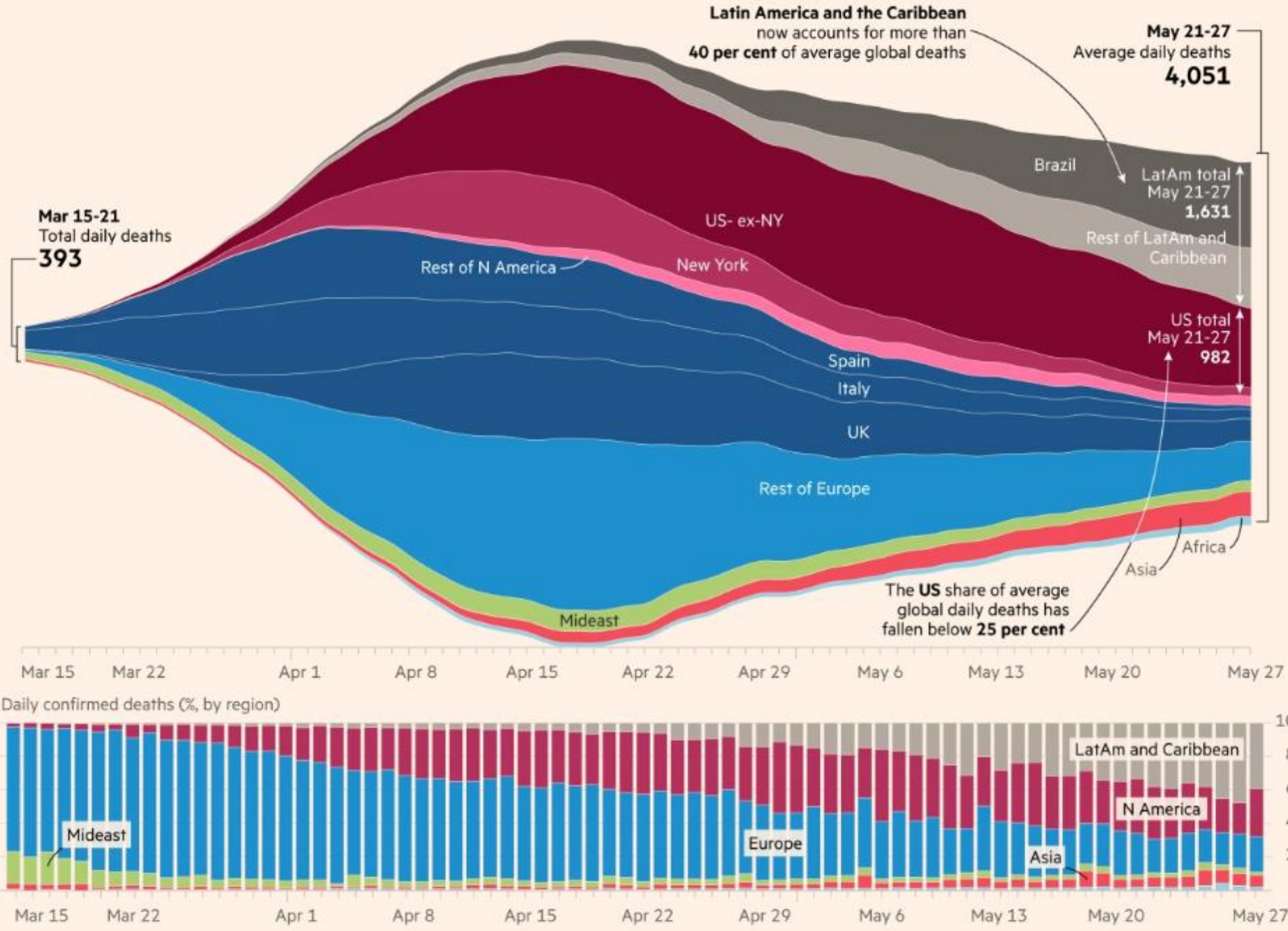
US new daily infections per mm people

Linear scale, 3 day trailing average



Source: Johns Hopkins University, IMF, JPMAM. May 27, 2020

Daily deaths of patients diagnosed with coronavirus (7-day average)



May 2020

FT graphic: Steven Bernard / @sdbernard
Source: FT analysis of ECDC and Covid Tracking Project data
© FT

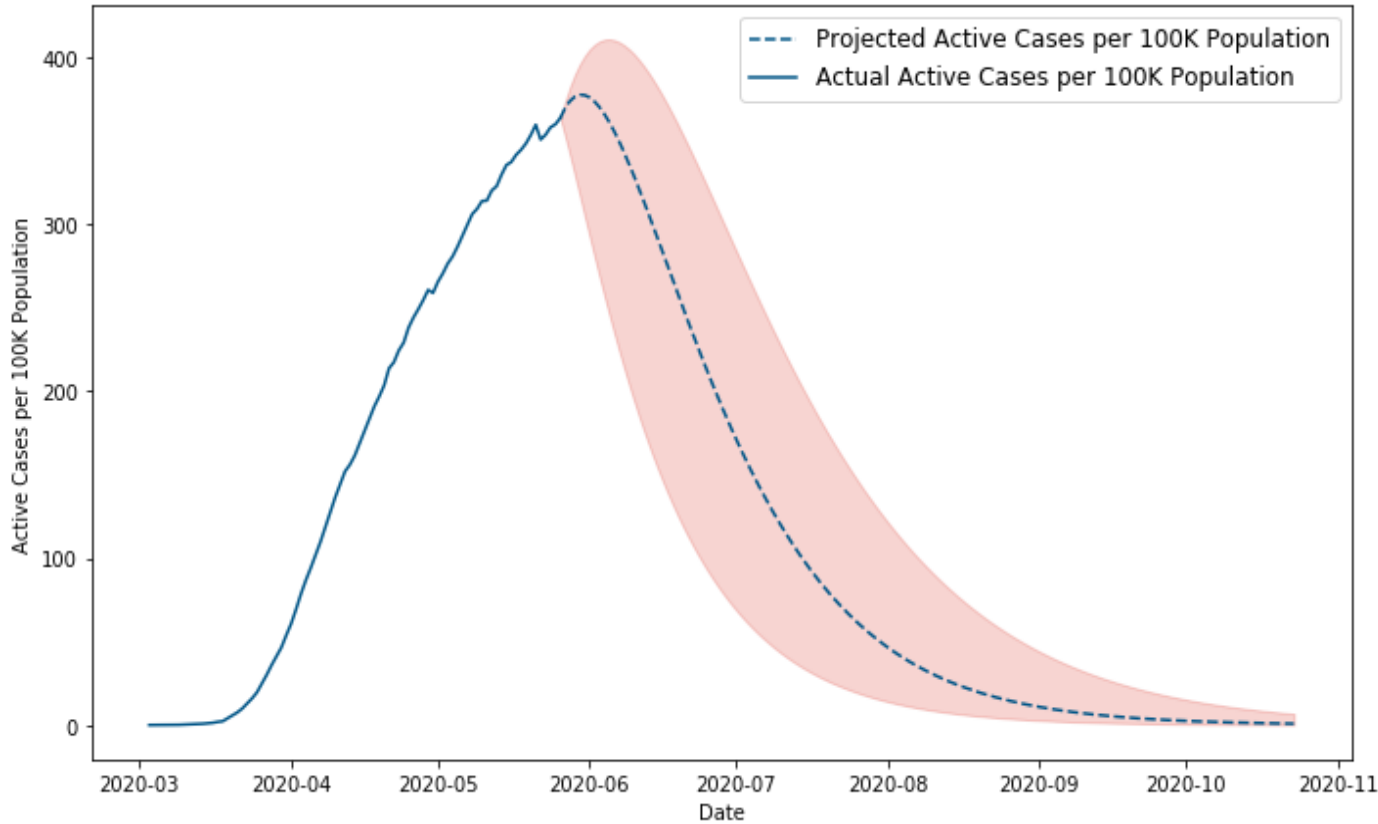


Cases Curve Simulator

- This COVID-19 Active Cases Curve Simulator has been developed by the IQVIA Data Science and Advanced Analytics team as a tool to help stakeholders make decisions based on the level and trajectory of active cases in their country, region or state
- The core of the model is the Susceptible-Exposed-Infectious-Removed epidemiology model, and inputs are from publicly available sources updated daily
- The simulator focuses on “total active cases” as a metric that speaks to the overall impact COVID-19 is having, not just limited to hospitalizations or deaths (where other models are focused, e.g. IHME). We believe the active cases curve will be used by public health officials – along with other considerations, such as availability of testing – to guide their decision-making on modifying stay-at-home rules
- Active cases are those confirmed diagnosed cases, excluded those that have recovered or died.
- The simulation shows the number of active cases (per population), shape of increase of the curve, timing of the apex of the curve and the shape and timing of the decline from the apex.
- Scenarios are labelled as “normal”, “optimistic” and “pessimistic” based on the following
- “Normal” scenario means the model parameters are derived to fit most closely to the actual reported public data
- “Optimistic” scenario is the lower bound, assuming people closely follow nonpharmaceutical interventions (NPIs), and reference what was achieved in other countries with similar characteristics
- “Pessimistic” scenario is the upper bound, assuming people do not closely follow NPIs and time from exposure to diagnosis takes longer than reported in the literature

Source: IQVIA, April 2020

Simulation band of active cases in next 150 days in U.S.



Optimistic Scenario

Normal Scenario

Pessimistic Scenario

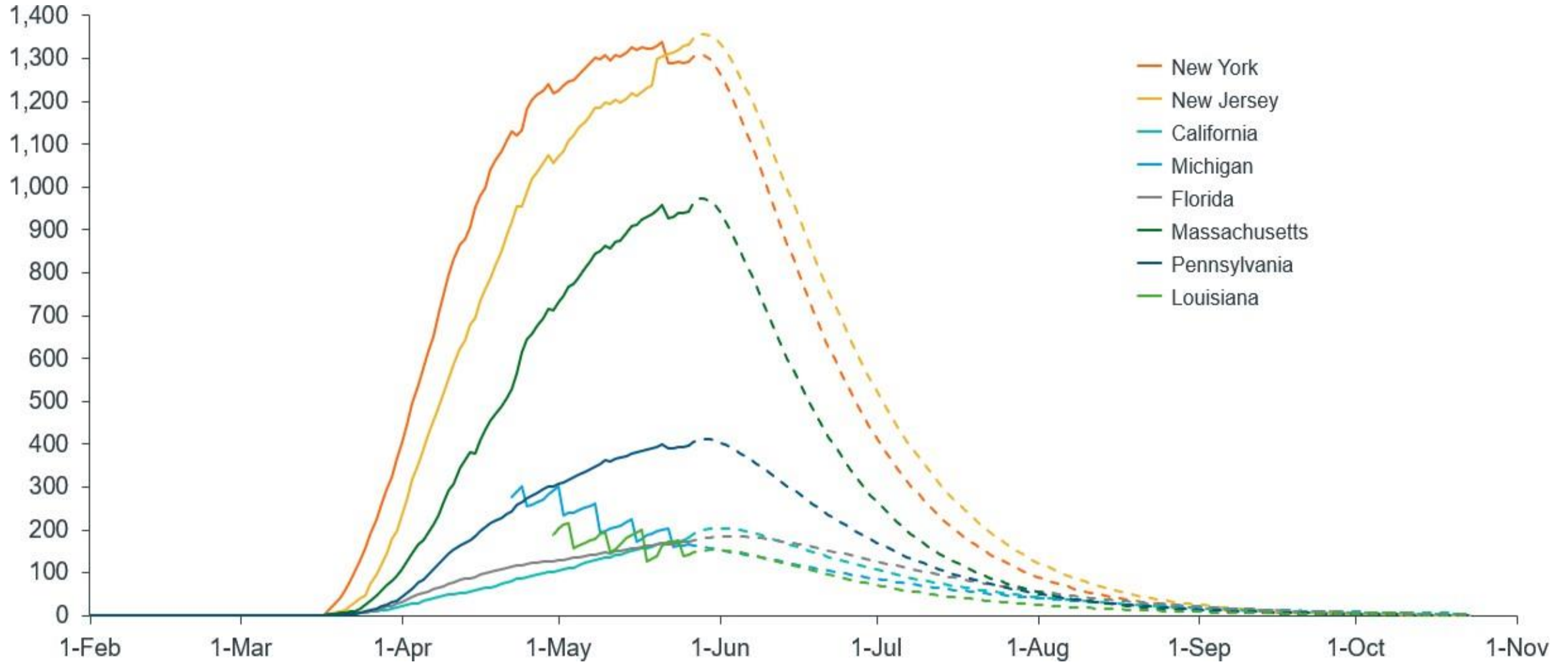
	Projected total confirmed cases	Projected total confirmed cases per 100k population	Estimated Peak time
Optimistic Scenario	1.8M	558.3	5/27/2020
Normal Scenario	2.9M	889.3	5/30/2020
Pessimistic Scenario	3.5M	1072.7	6/5/2020

Source: IQVIA, May27, 2020



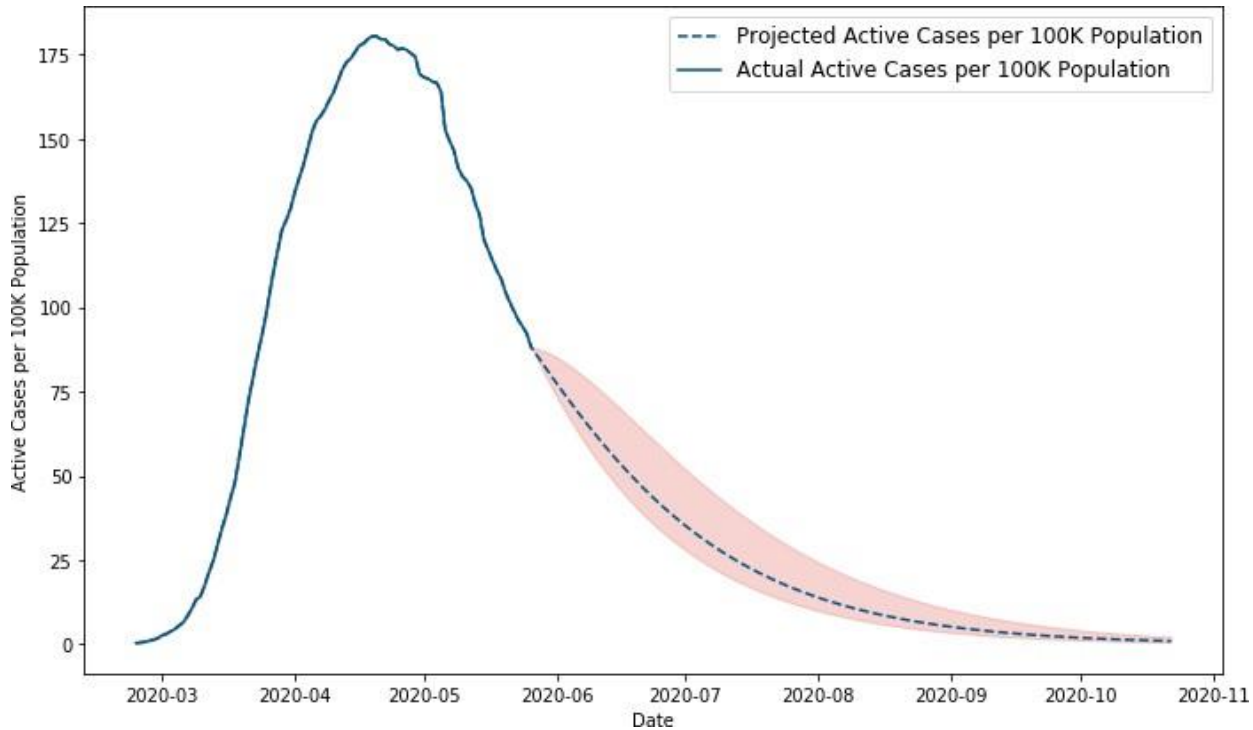
May 2020

Simulation of active cases per 100k population in next 150 days in US



Source: IQVIA, May27, 2020

Simulation band of active cases in next 150 days in Italy



	Projected Total Confirmed Cases	Projected total confirmed cases per 100K population	Estimated peak time
Optimistic Scenario	233.2K	388.6	4/19/2020
Normal Scenario	243.8K	406.3	4/19/2020
Pessimistic Scenario	270.2K	450.3	4/19/2020

Source: IQVIA, May27, 2020



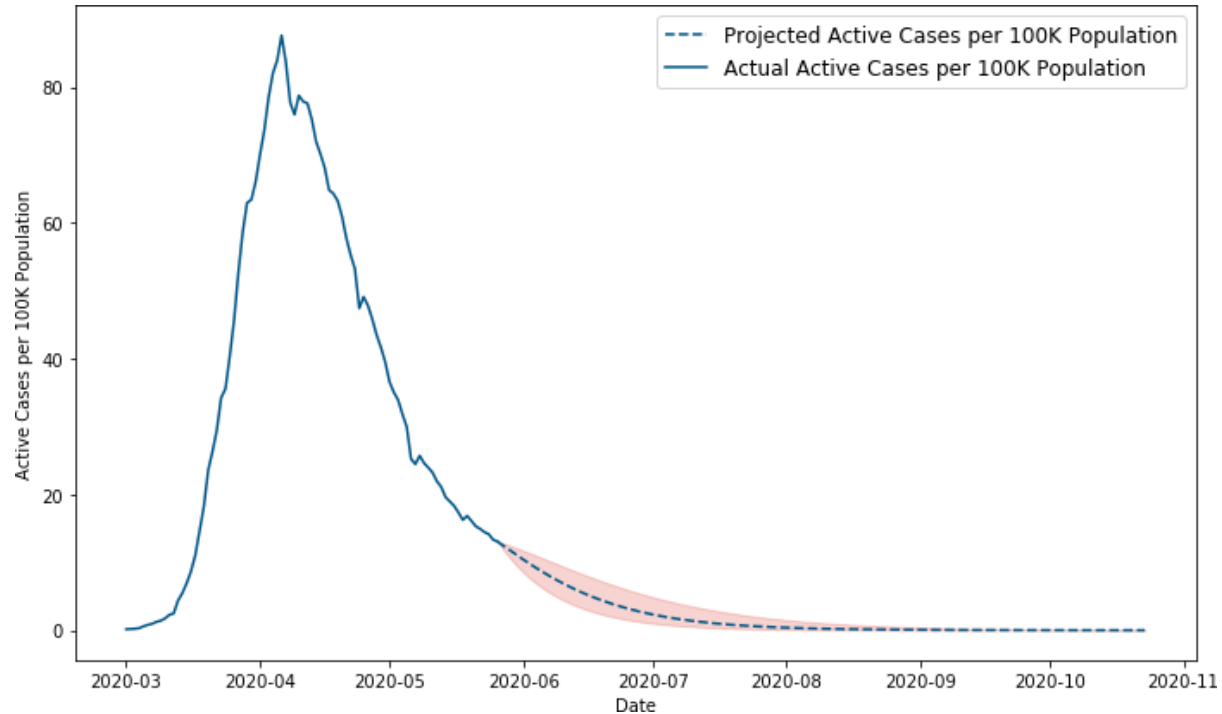
May 2020

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In it for life

Simulation band of active cases in next 150 days in Germany



	Projected Total Confirmed Cases	Projected Total Confirmed Cases per 100k Population	Estimated Peak Time
Optimistic Scenario	185.2K	222.7	04/06/2020
Normal Scenario	186.8K	224.7	04/06/2020
Pessimistic Scenario	189.0K	227.3	04/06/2020

Source: IQVIA, May27, 2020



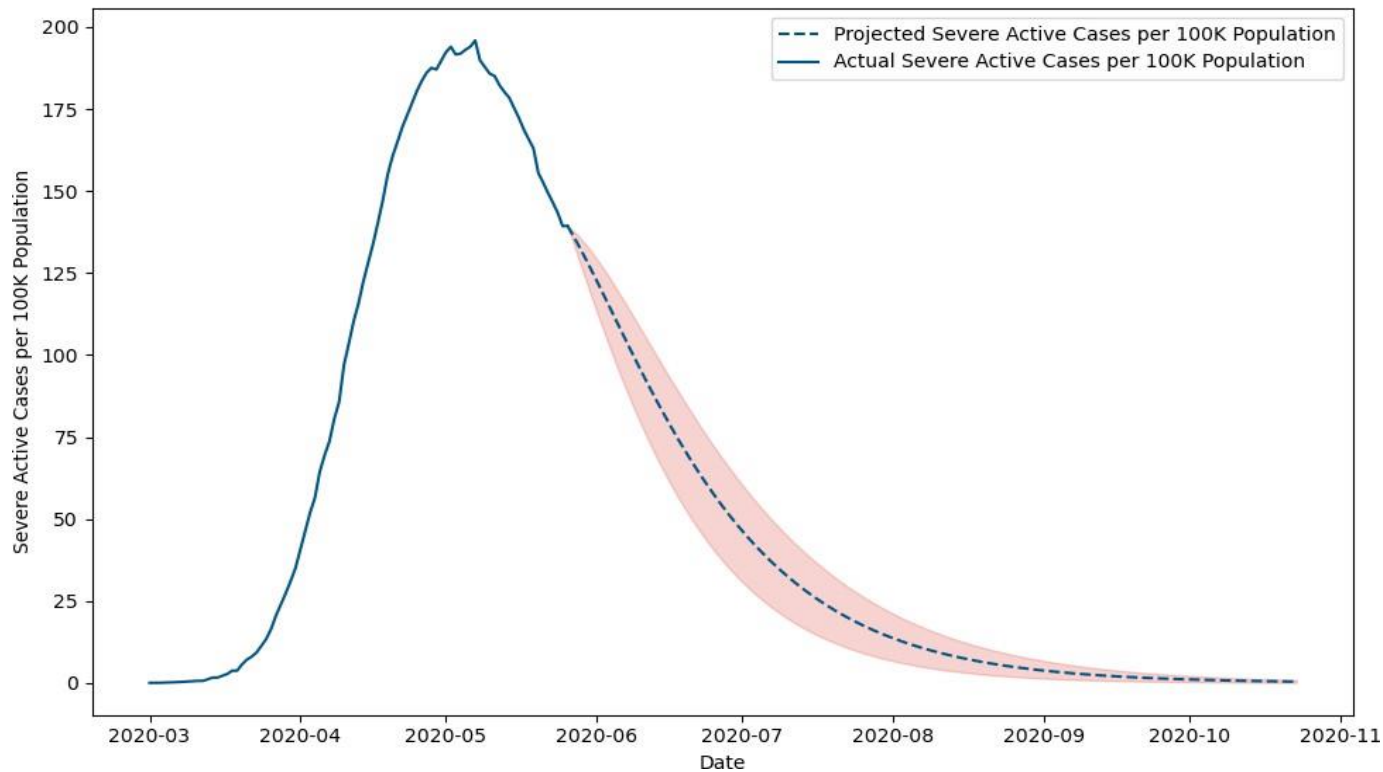
May 2020

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In it for life

Simulation band of severe active cases in next 150 days in UK



	Projected Total Severe Confirmed Cases	Projected Total Severe Confirmed Cases per 100k Population	Estimated Peak Time
Optimistic Scenario	285.6K	429.9	05/07/2020
Normal Scenario	295.8K	445.2	05/07/2020
Pessimistic Scenario	311.5K	468.9	05/07/2020

Source: IQVIA, May27, 2020



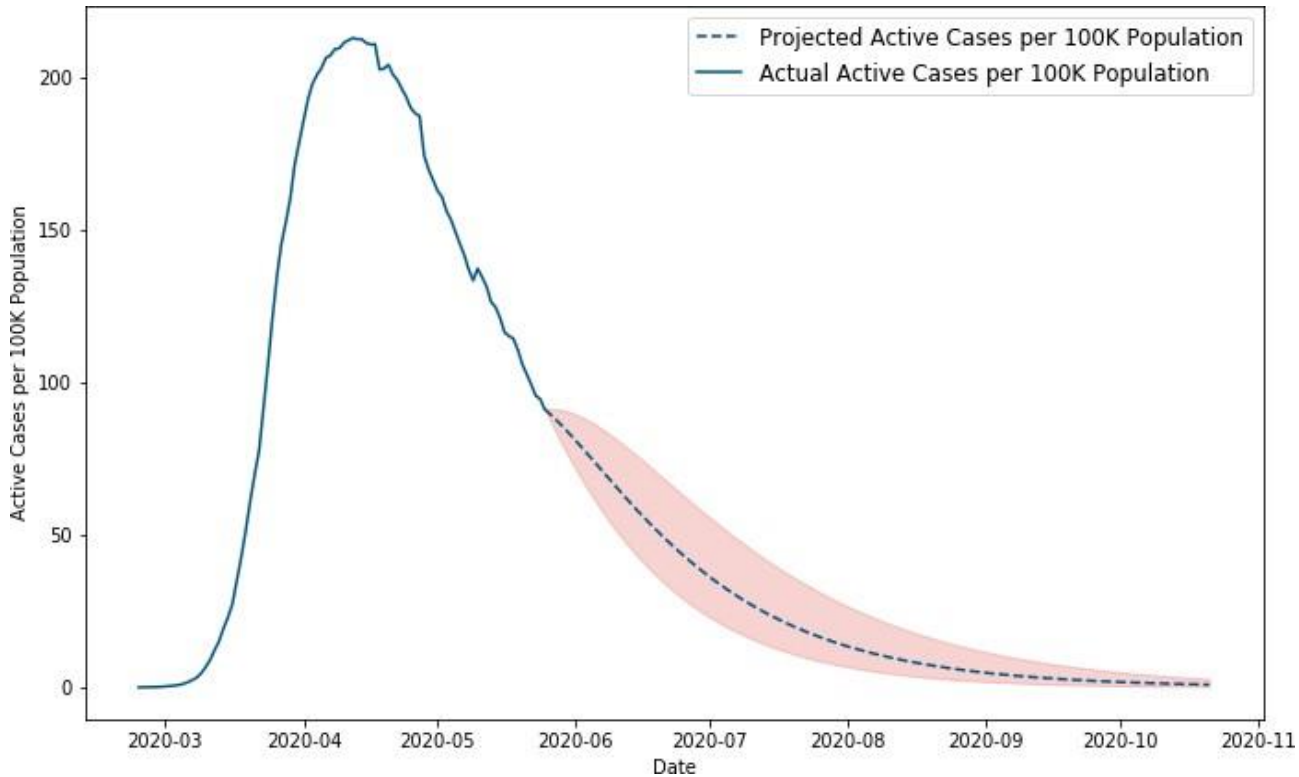
May 2020

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In it for life

Simulation band of active cases in next 150 days in Spain



	Projected Total Confirmed Cases	Projected Total Confirmed Cases per 100k Population	Estimated Peak Time
Optimistic Scenario	240.1K	516.3	04/17/2020
Normal Scenario	247.7K	532.7	04/17/2020
Pessimistic Scenario	261.7K	562.7	04/17/2020

Source: IQVIA, May27, 2020



May 2020

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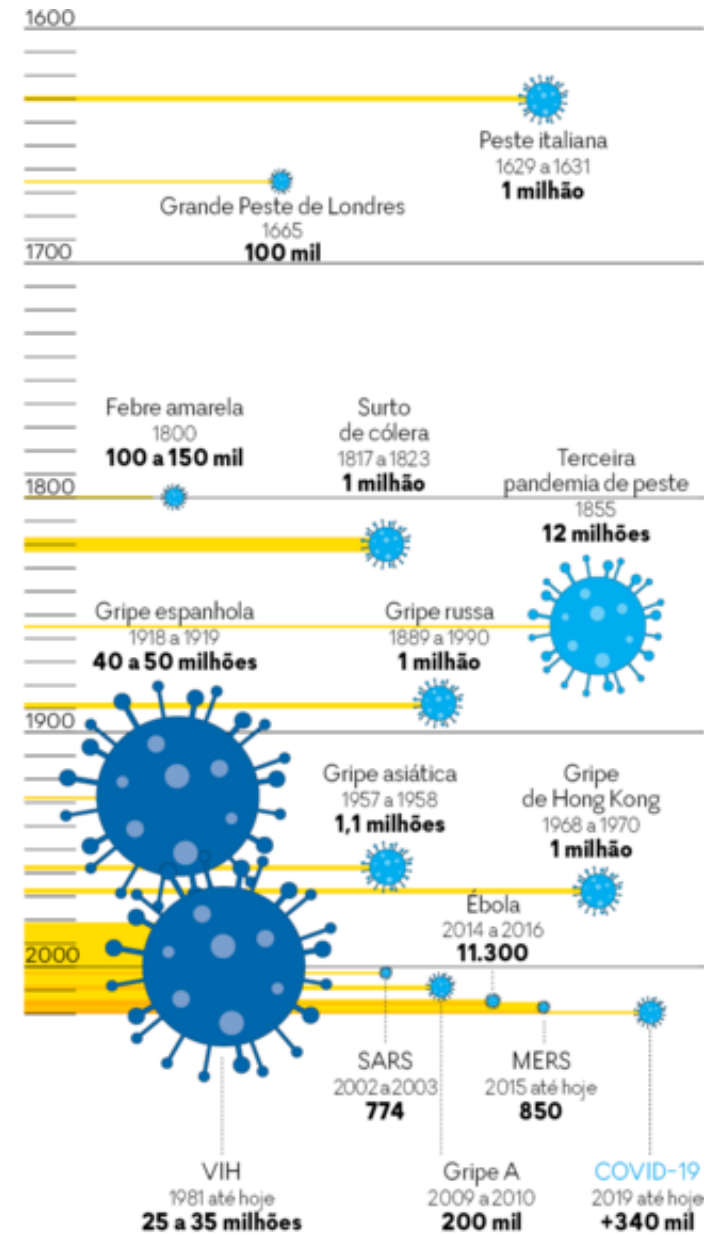
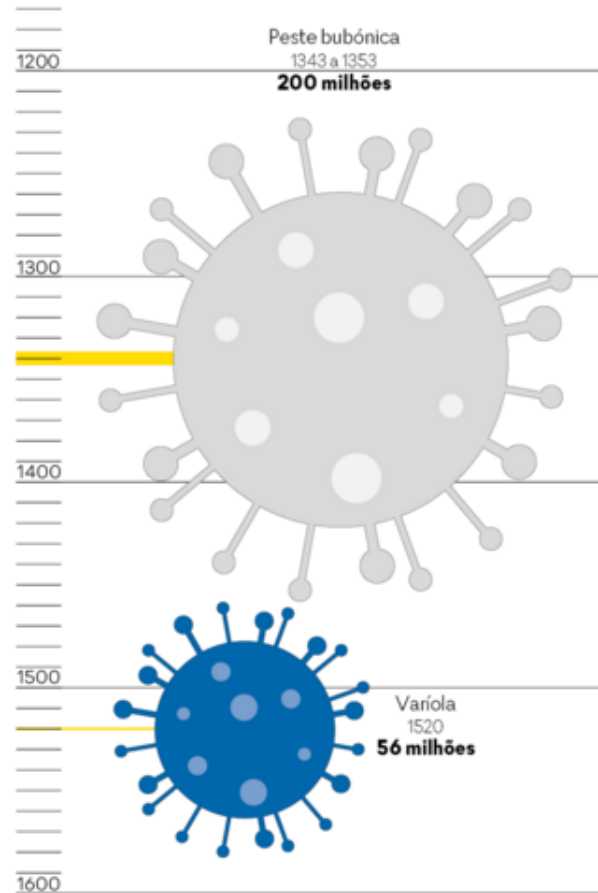
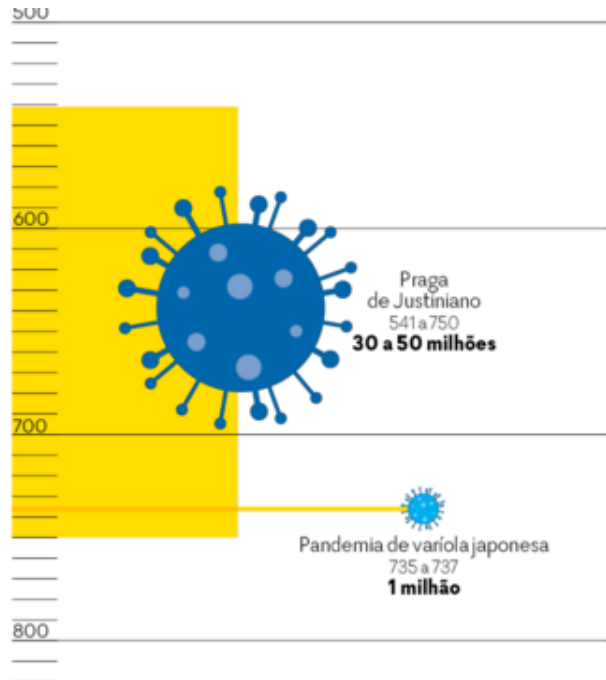
33

In it for life

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain...

- **28 May**
 - Oxford Biomedica penned a one-year clinical and commercial supply deal with AstraZeneca to scale up manufacturing for the COVID-19 vaccine candidate AZD1222.
 - Roche announced a new partnership with Gilead as the drugmakers started a phase III study testing the Swiss drugmaker's immunology med Actemra/RoActemra alongside Gilead's antiviral remdesivir to treat COVID-19. Roche plans to begin enrollment in June, with a target of 450 patients globally.
 - Moderna expanded a 2016 deal with Swiss pharmaceutical ingredient maker CordenPharma on Thursday to secure large quantities of lipids for its experimental COVID-19 vaccine mRNA-1273. The deal grants access to two additional CordenPharma manufacturing sites in France and the U.S. as Moderna looks to boost its vaccine stores in anticipation of success in the clinic.
 - GlaxoSmithKline (GSK) has announced it will manufacture one billion doses of its pandemic adjuvant by 2020. Although GSK is not producing its own Covid-19 vaccine, it is supporting on a non-profit basis other companies who are with its pandemic adjuvant. During previous flu pandemic, this part of the vaccine, which boosts the immune response, was shown to reduce the amount of protein needed per dose, therefore allowing more doses to be produced.
- **27 May**
 - The World Health Organization is putting a stop to global studies into the effectiveness of hydroxychloroquine after repeated safety concerns. The decision came following a study published in The Lancet that showed patients who took hydroxychloroquine were at higher risk of death and heart problems than those who did not.
- **26 May**
 - Gilead's remdesivir has shown promising results, but some limits, too. Detailed data published in the New England Journal of Medicine showed that on average, hospitalized patients receiving remdesivir recovered a median of four days faster than patients on placebo, with mortality in the remdesivir group at 7.1% compared to the placebo group's 11.9%. But the data also suggest the drug offers more benefits to patients on oxygen therapy than to the critically ill on mechanical ventilators.
 - The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) has granted early access to remdesivir in its medicines scheme for conditions with a high unmet medical need.
- **25 May**
 - Like all industries, the pharma industry has been disrupted by the Covid-19 pandemic. The generics industry has been impacted particularly by supply chain problems and huge surges in demand for existing medicines.
 - Accord's head of scientific affairs Dr Anthony Grosso explains how the industry has worked to overcome these challenges and respond to the needs of patients, as well as become more prepared for future healthcare emergencies.
- **24 May**
 - Experts across world continue to highlight the need to reopen economies to limit the economic upheaval caused by the Covid-19 pandemic.
 - However, some believe that unless testing capabilities are ramped up, reopening the economy may result in an upsurge in infection rate.

Pandemics – Number of Deaths



Source: Expresso - <https://expresso.pt/coronavirus/2020-05-15-Covid-19.-O-maior-aumento-de-novos-casos-dos-ultimos-sete-dias-o-surto-em-Portugal--em-graficos-e-mapas->

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

- **22 May**
 - Beximco Pharma launches first generic remdesivir for Covid-19, under the brand name Bemsivir.
- **21 May**
 - AstraZeneca has secured over \$1 billion from the HHS' BARDA for the development and supply of the Oxford University vaccine it has partnered on.
 - Moderna is currently the leader in the mRNA vaccine space, but Evercore ISI analyst Umer Raffat is raising doubts about the strength of the preliminary phase 1 data the biotech recently posted.
 - AstraZeneca has previously also invested in Moderna.
 - The unemployment rate in the US currently stands at 14.7% but for people aged between 20 and 24, the rate increases to 25.7%, according to statistics provided by the BLS.
- **20 May**
 - People with Type 1 diabetes are three and a half times more likely to die than non-diabetics who catch COVID-19 while Type 2 patients are twice as likely to die than non-diabetics, NHS England has found.
- **19 May**
 - Gilead Sciences has pledged to donate its current supply of 1.5 million doses of remdesivir, of which 607,000 vials are being allocated to the U.S. government. Now, the biotech is increasing its U.S. donation to about 940,000 doses by June.
 - The Trump administration has signed a \$354 million four-year deal with a new Virginia company called Phlow to produce generic drugs and APIs needed to treat COVID-19 in an effort to bring pharma manufacturing back to the U.S.
 - Meanwhile, Cipla, which is one of four drugmakers with nonexclusive remdesivir licensing deals, is also looking at combo treatment options for COVID-19, including teaming Fujifilm's flu drug Avigan (favipiravir) with the Gilead med.
- **18 May**
 - Moderna shares leapt as the company unveiled early phase 1 data showing its vaccine candidate, mRNA-1273, elicited neutralizing antibodies in eight trial participants available for analysis. Based on the data, The company said its own phase 2 trial will be amended to study two dose levels, 50 µg and 100 µg.
 - On the heels of unveiling early results for its mRNA vaccine, Moderna plans to raise \$1.34 billion through a stock sale to help produce the shot if it crosses the regulatory finish line.
 - Moncef Slaoui, the newly appointed U.S. coronavirus czar, will divest his \$10 million in Moderna stock options, which shot up in value Monday after the company unveiled promising early data.
- **17 May**
 - The EU could grant Gilead's remdesivir an conditional nod in the "coming days," EMA head Guido Rasi said on Monday at a hearing at the EU Parliament in Brussels.

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

- **14 May**
 - After a fast-tracked approval, Japan has already started distributing Gilead Sciences' remdesivir to hospitals. The drug is being used for patients in intensive care or on ventilators.
 - The United Nations's International Labour Organization predicts 1.6bn informal economy workers could suffer "massive damage" to their livelihoods.
 - In the second quarter of 2020, Covid-19 may cost the equivalent of 305 million full-time jobs.
 - Current G7 jobless totals vary widely, from 30 million in the United States to 1.76 million in Japan.
 - McKinsey believe that Europe's CEOs will have to draw on the region's spirit of innovation to recover post Covid-19.
- **13 May**
 - The US Food and Drug Administration (FDA) has granted fast track designation to Moderna's Covid-19 vaccine candidate, mRNA-1273.
 - Even if Moderna succeeds with its unproven vaccine platform, the biotech won't be able to make enough doses for the entire world, CEO Stephane Bancel said.
 - After Gilead inked a series of licensing deals for remdesivir, Public Citizen argued the drug should be in the public domain.
- **12 May**
 - Gilead inked licensing deals with generic drugmakers Cipla, Ferozsons Laboratories, Hetero Labs, Jubilant Lifesciences and Mylan allowing those companies to manufacture and distribute remdesivir in 127 countries, royalty-free.
 - The European Medicines Agency expanded its compassionate use guidelines for Gilead's remdesivir. Originally, the drug was recommended for patients requiring mechanical ventilation. It's now recommended for certain hospitalized patients.
- **11 May**
 - Physicians and hospitals have already expressed frustrations about the difficulty obtaining Gilead Sciences' remdesivir. Now, an HHS distribution plan shows that only 607,000 vials of the emergency use drug will be made available to U.S. patients over the next six weeks, out of a total donation of about 1.5 million
- **9 May**
 - Gilead Sciences may have been the target of Iranian hackers using fake email login pages to access confidential data, Reuters reported. In one case, a fake login page was sent to a legal and corporate affairs executive in April. Reuters couldn't confirm whether the attack was successful.
 - Speaking of Gilead, the National Institutes of Health will pair the drugmaker's COVID-19 antiviral remdesivir with Eli Lilly's rheumatoid arthritis drug Olumiant in a new study in U.S. hospitalized patients. The trial will eventually enroll 1,000 patients across 100 sites, the NIH said.
 - After the FDA's emergency use authorization, Gilead donated its entire stockpile of remdesivir to the government for further distribution. But the drug hasn't reached those most in need, according to Axios. "Some went to the wrong places, some went to the right places," one senior Trump administration official said. "We don't know who gave the order. And no one is claiming responsibility."

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

- **8 May**
 - Hydroxychloroquine has failed an observational study in New York. According to a paper published in The New England Journal of Medicine, researchers found no significant difference between hydroxychloroquine and standard care in terms of patients' need for ventilation or death rate.
 - After the FDA's emergency use authorization, Gilead has donated its entire stockpile of remdesivir to the government for further distribution.
 - FDA authorises Moderna to conduct Phase II trial of Covid-19 vaccine
- **7 May**
 - Gilead Sciences' remdesivir won approval in Japan as Veklury. It's the first full global nod for the COVID-19 treatment following the U.S. emergency use authorization last week. Authorities in Japan approved the drug under an "exceptional approval" regulatory pathway.
 - Gilead spent about \$50 million on remdesivir manufacturing scale-up and clinical trial costs during the first quarter.
 - Moderna is planning an "imminent" start to a 600-participant phase 2 trial of its mRNA vaccine candidate, mRNA-1273, after the FDA cleared its trial protocol. The company's goal is to initiate a phase 3 study "early this summer" and win approval as soon as 2021.
- **6 May**
 - Gilead Sciences says it's in licensing talks with the "world's leading chemical and pharmaceutical manufacturing companies" about their ability to produce remdesivir for countries in Europe, Asia and beyond until at least 2022.
 - Scientists have identified a new strain of the coronavirus that appears to be more contagious than the early versions in the pandemic, according to a new study led by scientists at Los Alamos National Laboratory.
- **5 May**
 - A drugmaker in Bangladesh, Beximco, plans to start making Gilead's newly FDA-authorized remdesivir for \$59 to \$71 per vial, Reuters reports. The company is planning to produce the drug for domestic use, at least initially. It isn't clear whether Beximco had a licensing deal to manufacture the product.
- **4 May**
 - How much should Gilead Sciences charge for remdesivir? Up to \$4,460 per patient, according to the Institute for Clinical and Economic Review. But even at \$1,000 per patient—less than a quarter of ICER's pitched price—Gilead could theoretically rake in \$1 billion in sales, as it looks to build a supply capable of treating 1 million patients by the end of the year.
- **2 May**
 - Moderna Therapeutics has tapped Lonza to help manufacture the biotech's mRNA vaccine candidate, dubbed mRNA-1273.

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

• 30 April

- Economic Outlook: Covid-19 puts 1.6 billion jobs at risk – Q1 company earnings 'most watched in history' say Goldman Sachs.
- GDP of majority of the economies to be below pre-Covid-19 levels for two to three years.
- Gilead's remdesivir meets endpoint in NIAID study.
- GlobalData Epidemiologist Report – Covid-19 now affects 187 countries – over 1 million cases in US

• 29 April

- The US economy has contracted at an annual rate of 4.8%, the steepest slump since the 2008 recession. This brings the longest ever period of economic expansion in the US to an end.
- It is predicted that gross domestic product (GDP) could drop by 30% in the next quarter, as many "stay-at-home" measures were only implemented at the end of this quarter, with a sharp rise in unemployment also anticipated.

• 28 April

- On the back of disappointing results for Sanofi and Regeneron's IL-6 inhibitor, Kevzara yesterday, a research team from the Assistance Publique-Hôpitaux de Paris announced that an open-label, randomized, controlled study of Roche's Actemra in 129 moderate to severe COVID-19 patients with pneumonia was successful.
- UK Approves Clinical Trial Of Plasma Therapy for COVID-19.
- Covid-19's impact on drug contract manufacture in Italy. GlobalData's Contract Service Provider database shows there are 148 CMOs with Italian facilities

• 27 April

- Another high profile drug being repurposed for COVID-19 treatment faced a major setback this morning. Sanofi and Regeneron's IL-6 inhibitor, Kevzara showed no benefit in "severe" COVID-19 patients requiring oxygen therapy.
- China has granted approval to assess a third coronavirus vaccine candidate against COVID-19 in the second phase of clinical trials.
- Vaccine major Serum Institute of India on Sunday said it plans to start production of the COVID-19 vaccine developed by Oxford University in the next two to three weeks and hopes to bring it to the market by October if the human clinical trials are successful.
- France, Italy and Spain announce easing of lockdown measures.

• 24 April

- On April 23rd, news broke of a potential failure of Gilead's COVID-19 candidate, remdesivir, to improve mortality in hospitalized adult patients with severe COVID-19 from a trial in China. However, any data reported here must be approached with caution, as the full results of the study have not yet been made available, and what has been released is from a trial which was terminated due to difficulties in recruitment.

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

- **23 April**

- Gilead's remdesivir has failed to show benefit in a clinical trial conducted to treat Covid-19 patients in China, according to data the WHO accidentally posted on its website.
- Preliminary reports from epidemiological studies suggest that countries with universal BCG vaccination programs have been impacted less by Covid-19

- **22 April**

- The Covid-19 pandemic is expected to widen the gap between the poor and rich creating massive inequality and high unemployment rates.
- The world is on track for a recession of "unprecedented depth in the post-war period", ratings agency Fitch says with world gross domestic product to tumble by 3.9% in 2020.

- **21 April**

- Pharma CEOs are asking that governments pour out billions of dollars in advance for the development and production of potential COVID-19 drugs.
- Following other companies such as Pfizer and Novo Nordisk, Merck & Co. is now also expanding its patient assistance program, allowing eligible patients to get its medicines at no cost.
- To ease shortages of drugs for COVID-19 patients who are on ventilators, the FDA is now allowing small compound pharmacies to temporarily fill the supply gap.

- **20 April**

- Researchers at the NIH and Gilead have published results from an animal trial of remdesivir, involving 12 rhesus macaques, showing that early antiviral treatment reduced COVID-19 symptoms and lung damage.
- Though the COVID-19 pandemic has upended the public markets—and thrown a wrench into what was expected to be a stellar IPO season—the biotech industry could be that particular cloud's silver lining, as investors look toward additional windows and opportunities later this year.
- A congressman is calling on the SEC to investigate last week's leak of remdesivir data, along with its impact on the stock market and a 15% boost in Gilead's share price. Though the antiviral is not supposed to be a moneymaker for the Big Pharma, news following its development has added billions to Gilead's market cap.
- The FDA has granted emergency use authorizations to four antibody diagnostics—also known as serology tests—that promise to help identify individuals who have been exposed to the novel coronavirus.

- **19 April**

- Meanwhile, in the U.S., the FDA has stepped up seizures of prescription drugs being sent to American customers from Canada and other countries, where they are sold at cheaper prices, according to Kaiser Health News.

- **18 April**

- In the European region, it's notable that the number of cases are increasing in Belgium with a total of 34,809 cases, placing the country in rank just after the UK, though the gap between the two countries is large.

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

• 17 April

- BARDA supports Moderna's vaccine.
- Promise of Gilead's remdesivir made clear.
- Nasal spray vaccine on the horizon.

• 16 April

- Millions of doses of hydroxychloroquine donated to the U.S. by Bayer have come under scrutiny after the quality of the drug's Indian and Pakistani active pharmaceutical ingredients and finished doses may have never passed FDA inspections, sources told Reuters. Bayer has donated 3 million tablets of the drug, called Resochin, to the U.S. national stockpile for treatment of COVID-19.
- Despite the fact that Fujifilm's Avigan hasn't been proven as an effective COVID-19 treatment, Japan and China are providing the drug to other countries, the Wall Street Journal reports.

• 15 April

- India is hoping to rapidly expand its production of global active pharmaceutical ingredients to compete with China's dominance in the market amid COVID-19 lockdowns, Bloomberg reported. The country is one of the largest providers of generic drugs to the U.S.
- Gilead Sciences is among the companies with promising COVID-19 drugs and the company has now applied for a trademark for potential remdesivir packaging. But at press time, the company's shares were down on word that a second China trial had been stopped for lack of enrollment.
- As the White House's Tuesday press briefing, President Donald Trump said the U.S. is halting funding to the World Health Organization. Bill Gates and others blasted the move.

• 14 April

- China's National Medical Products Administration has greenlit two inactivated COVID-19 vaccines to start human testings.
- Sanofi and GSK, two of the world's biggest vaccine makers, are joining forces to develop a recombinant DNA vaccine, aiming to enter clinical testing in the second half of 2020.

• 13 April

- Rutgers University has received the FDA's first emergency authorization for a COVID-19 diagnostic that uses easy-to-collect saliva samples instead of the more difficult deep nose swabs.
- Gilead provided results from 53 severe COVID-19 patients treated with remdesivir on a compassionate use basis in a paper published in The New England Journal of Medicine. During a median follow-up of 18 days, 36 patients (68%) had a clinical improvement, and the mortality rate was 18% among patients receiving invasive ventilation. Jefferies analysts argue the data "suggest remdesivir may work and is generally safe."

• 10 April

- Gilead's promising COVID-19 drug candidate remdesivir could be made at \$9 per treatment, while the estimated manufacturing cost for generic hydroxychloroquine stands as little as \$1 per course, a study published in the Journal of Virus Eradication found.

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

- **9 April**
 - Pfizer says a Phase 2 investigator-initiated study for the use of tofacitinib, a JAK inhibitor, in patients with SARS-CoV-2 interstitial pneumonia is about to start in Italy.
 - Mylan says its expedited manufacturing of hydroxychloroquine has resulted in stocks being available ahead of schedule.
 - Analysts at Morningstar say the coronavirus pandemic will affect Big Pharma and Big Biotech companies in two major ways: an economic slowdown, likely causing a 4.6% hit to 2020 global GDP (implying a 1.4% decline in 2020), and a disruption in the use of drugs, vaccines, and consumer healthcare products. “However, the highly inelastic demand for most drugs should largely offset any recessionary impact,” they add.
- **8 April**
 - The European Commission publishes its guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak.
 - US Food and Drug Administration commissioner Stephen Hahn says that since the agency issued its policy to allow developers of serological tests to identify patients that have developed an immune response to market them without FDA review, over 70 tests are available for use.
- **7 April**
 - Bristol Myers Squibb announces an expansion of its patient support programs to help unemployed US patients who have lost their health insurance due to the COVID-19 pandemic.
- **6 April**
 - India lifts export restrictions on 12 APIs and their formulations including antibiotics, vitamins and hormones with immediate effect, according to a Directorate General of Foreign Trade notification. Paracetamol and hydroxychloroquine are notable omissions from the list.
 - Thermo Fisher Scientific says that due to the COVID-19 pandemic, it is withdrawing its 2020 annual financial guidance, which was provided on January 30. “As the pandemic spread from China to countries worldwide, the company saw a significant reduction in customer activity by late March.
- **4 April**
 - In an open letter, Gilead CEO Daniel O’Day says the biotech company has managed to reduce the end-to-end manufacturing timeline for its antiviral remdesivir – which has shown potential to treat patients with severe COVID-19 -- from one year to around six months.
 - India’s Directorate General of Foreign Trade announces an immediate blanket ban on exports of hydroxychloroquine “without any exceptions.”

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

- **3 April**
 - Generics industry association Medicines for Europe supports a call by the European University Hospital Alliance for European coordinated efforts to prevent shortages of ICU medicines – which include sedatives, muscle relaxants, antibiotics and anaesthetics -- amid rising demand.
 - Novartis says it plans to start a clinical trial of its JAK inhibitor, Jakavi (ruxolitinib), in patients with COVID-19 associated cytokine storm, a form of severe immune overreaction that can result from coronavirus infection.
- **2 April**
 - Roche Canada announces its COVID-19 Innovation Challenge, a competition to bring forward innovative ideas to fight the pandemic.
 - Amgen and Adaptive Biotechnologies announce a partnership to develop neutralizing antibodies targeting SARS-CoV-2 to potentially prevent or treat COVID-19.
 - The US Food and Drug Administration approves Celularity's Investigational New Drug application for its CYNK-001 cell therapy in adults with COVID-19.
 - The European Medicines Agency says chloroquine and hydroxychloroquine, currently authorised for malaria and certain autoimmune diseases but being investigated for their potential to treat COVID-19, should only be used in clinical trials or emergency use programmes.
- **1 April**
 - AbbVie is donating USD35 million to support COVID-19 relief efforts.
 - Gilead announces that it has started two Phase 3 studies of its investigational antiviral treatment, remdesivir, in patients with moderate to severe COVID-19 in the UK.
 - The US Food and Drug Administration says it has launched a program to speed up the development of treatments for COVID-19.
- **31 March**
 - The US government is in discussions with India over a possible relaxing of restrictions on API exports from India imposed at the start of March.
 - China is stepping up its efforts to produce and ship APIs with a focus on meeting international demand, particularly for those showing potential to treat the COVID-19 disease
- **30 March**
 - In a letter to customers, CordenPharma says it has halted routine manufacturing at its Bergamo facility in northern Italy for one week from 26 March to 1 April due to supply chain interruption and staffing issues.
 - Novartis announces that its generics unit Sandoz has started to ship 30 million doses of hydroxychloroquine to the US Department of Health and Human Services for use in clinical studies to test its effectiveness in people who have tested positive for COVID-19.

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

• 27 March

- Sanofi and Translate Bio are collaborating to develop a novel mRNA vaccine candidate against COVID-19, extending an existing 2018 agreement between the two firms on mRNA vaccines for infectious diseases.
- Wuxi Biologics says more than 98% of its staff are now back at work after the country's recent lockdown. The Chinese CDMO says it has received "a surge of requests" in March for new projects, predominantly from clients outside of China.

• 26 March

- The proposed merger Mylan and Pfizer's generics division, Upjohn, is postponed until the second half of 2020 due to the COVID-19 pandemic. Mylan's EGM has been pushed back two months to 30 June.
- A consortium of fifteen biopharma companies have agreed to share their proprietary libraries of drugs that already have promising safety and activity data with the COVID-19 Therapeutics Accelerator launched by the Gates Foundation, Wellcome, and Mastercard to quickly screen them for potential against COVID-19. The firms include BD, Boehringer Ingelheim, bioMerieux, Eisai, Eli Lilly, Gilead, GSK, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Pfizer and Sanofi.
- Mylan waives its right to a 180-day marketing exclusivity period in the US to distribute its generic version of antiretroviral Kaletra (lopinavir/ritonavir) to help increase the available supply of the product should it prove effective in treating patients with COVID-19.

• 25 March

- Medicines for Europe says export restrictions (including some within the EU) on drug and ingredients manufacturers is undermining European production. The generics industry body says its mid-February request for effective coordination between manufacturers and authorities to manage the crisis has not been fully realized. "We deeply regret that this process is not yet fully operational at EU or at national level except in Italy," it says.
- Vir Biotechnology announces that it has identified multiple human monoclonal antibody (mAb) development candidates that neutralize SARS-CoV-2, the virus responsible for COVID-19. The firm expects human trials to begin within 3-5 months.
- Suven Pharmaceuticals warns customers it cannot export finished products due to a shortage of raw materials following India's recent lockdown to fight COVID-19. Suven Pharmaceuticals warns customers it cannot export finished products due to a shortage of raw materials following India's recent lockdown to fight COVID-19.
- CDMO Catalent reaffirms it has not identified any significant risk or delay that may have a substantial effect on delivery of products or clinical trial supplies.

The latest coronavirus updates and developments impacting the global pharmaceutical supply chain... (cont.)

• 24 March

- Switzerland-headquartered CDMO Siegfried is supplying disinfectant in the Swiss and German regions where it operates production sites. It says it will not supply private or commercial organizations.
- In a letter to customers, CDMO CordenPharma says it has instructed all employees to cancel all business travel and face-to-face meetings until the end of April. It says all its manufacturing facilities in Italy, Germany, France, Switzerland and the US are fully operational.
- CMO Argonaut Manufacturing Services says it is ready to provide services for pre-clinical to Phase III manufacturing of vaccines and therapeutics, including those for firms working toward a COVID-19 vaccine or therapeutic under accelerated timelines.

• 23 March

- The International Generic and Biosimilar medicines Association, representing generic and biosimilar manufacturers, urges governments to reopen air freight routes to ensure access to medicines during the COVID-19 pandemic.
- Roche's Genentech in collaboration with the Biomedical Advanced Research and Development Authority says the FDA has approved a Phase III clinical trial of its arthritis drug Actemra (tocilizumab) to treat hospitalized adult patients with severe COVID-19 pneumonia.
- Eli Lilly becomes the first Big Pharma company to announce its clinical trials are being adversely affected by coronavirus. The firm says it is delaying most new study starts and pausing enrollment of new patients or volunteers "to ease the burden on participating healthcare facilities."

• 22 March

- Gilead says it is no longer accepting requests for emergency access to its antiviral remdesivir due to an "exponential increase" in such requests and "overwhelming demand."

• 21 March

- The Indian government approves a USD1.8 billion scheme to boost production of APIs and medical devices. The plan involves development of three mega API drug parks in partnership with states and financial incentives to manufacturers of 53 identified critical APIs on incremental sales for the next six years.
- In a filing to the Bombay Stock Exchange, Ipca Laboratories says the US FDA has lifted an import alert on its hydroxychloroquine sulphate and chloroquine phosphate APIs and hydroxychloroquine sulphate tablets due to the shortage implications of coronavirus.
- Bristol Myers Squibb says it has now implemented a mandatory work from home policy for its workforce. "All employees, contingent workers and contractors who can do their jobs from home must do so," it says.

Sources

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