

February 18, 2019

The Honorable Floyd Prozanski  
Chair, Senate Committee on Judiciary  
Oregon State Senate  
900 Court St. NE  
Salem, OR 97301

RE: Opposition to SB 703

Dear Chair Prozanski and members of the Committee on Judiciary:

IQVIA appreciates the opportunity to provide comments on Senate Bill 703. IQVIA is a leading global provider of research, advanced analytics and technology solutions to the life sciences industry, government agencies, academia, payers and other healthcare stakeholders. Formed through the merger of IMS Health and Quintiles, IQVIA applies human data science — leveraging the analytic rigor and clarity of data science to the ever-expanding scope of human science — to enable companies to reimagine and develop new approaches to clinical development, speed innovation and accelerate improvements in patient outcomes. IQVIA delivers unique and actionable insights at the intersection of large-scale analytics, transformative technology and extensive domain expertise. We research and report on various aspects of healthcare in more than 100 countries. Our research is informed by data sourced from more than 140,000 data suppliers covering approximately one billion data feeds globally.

IQVIA is also a global leader in protecting patient privacy. IQVIA privacy experts actively work with government officials and privacy policymakers throughout the world. The company uses a wide variety of privacy-enhancing technologies and safeguards to protect individual privacy while generating and analyzing information on a scale that helps healthcare stakeholders identify disease patterns and correlate with the precise treatment path and therapy needed for better outcomes. IQVIA's insights and execution capabilities help biotech, medical device and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders tap into a deeper understanding of diseases, human behaviors and scientific advances, in an effort to advance their path toward cures. For more than sixty years, IQVIA has supported the protection of patient privacy through its use of non-identified patient data in countries around the world for its syndicated research offerings.

Protecting an individual's health information is critical to a functional, effective healthcare system. Laws such as the Health Insurance Portability and Accountability Act (HIPAA) and existing state laws ensure there are appropriate protections for sensitive health information. These laws also recognize the critical role of real world non-identified information to improve healthcare --- to understand what really works to improve patient outcomes, lower healthcare costs, find new treatments and improve access to care. HIPAA enables the protection of individual data while also ensuring real world non-identified information may be used by researchers and health providers to advance scientific innovation and provide patients the care they need.

We are gratified to join a number of respected organizations in raising concerns about how this proposed law would upset that delicate balance. Organizations representing Oregon's healthcare providers have joined together with leading health plans, biopharmaceutical companies, clinical research organizations, civil rights advocates and others. We have come together to suggest caution in making such a sweeping change. This broad-based coalition is evidence of the importance that both protecting individual privacy and maintaining access to non-identified data have to the continued strengthening of our healthcare system.

### **SB 703 Will Disrupt Substantial Amounts of Research Necessary to Improve Healthcare**

Non-identified data provided by commercial organizations and used by all types of stakeholders for many purposes provides a wide array of tangible benefits to society. This data is critically important to understand our medical system and how it is performing. Many healthcare stakeholders in industry, government, academia and elsewhere routinely employ this data to examine healthcare delivery more closely and set policy or define actions that will improve care, access, outcomes and costs.<sup>1</sup> According to a report by the IMS Institute for Healthcare Informatics in 2015<sup>2</sup>, following are the top five uses of non-identified data from commercial organizations:

- **Guiding Strategy**: for example, the CDC used IQVIA data to reduce antimicrobial resistance by supporting antibiotic appropriate use initiatives
- **Identifying Public Health Issues**: for example, the FDA, the DEA, the AMA and other stakeholders in the U.S. use IQVIA data to help save lives by improving their understanding of the opioid crisis and help measure the success of Federal, state and other initiatives
- **Ensuring Drug Safety**: for example, the use of IQVIA data by manufacturers, distributors and government agencies to reduce counterfeit medicines, and fraud and diversion associated with medicines
- **Target Interventions**: for example, the use of IQVIA data to combat the prescription drug abuse epidemic by understanding patient behaviors and steps medical professionals and others can take
- **Improving Policy**: for example, the use of IQVIA data to improve care and decrease hospital readmission rates

Other uses of non-identified data include:

- Use of data to bring new medicines to market faster through improved clinical trial design (e.g., use of inclusion and exclusion criteria that matches real world patient populations); improved site selection for clinical trials; improved investigator and patient recruitment for participation in clinical trials; and use of real world data for alternative control arms (i.e., reduces the number of patients required to participate in a clinical trial)
- Study comparative effectiveness of medicines
- Study comparative effectiveness of treatment protocols and patient care
- Study patient sub-populations response and risk
- Identify health disparities and improve the effectiveness and accessibility of healthcare<sup>3</sup>

- Compare physician performance and quality
- Monitor post-marketing safety and adverse events to support regulatory decisions
- Benchmark national and regional performance
- Identify knowledge gaps

A substantial amount of this work is performed using non-identified data from IQVIA and other commercial organizations. Commercial organizations gather non-identified information from a wide variety of sources to build comprehensive databases from which this research can be performed on a wide range of topics by a wide range of stakeholders. It took many years to establish the data supply networks used today to support these databases. Each data supply arrangement requires substantial due diligence, testing, implementation of privacy-enhancing technologies and safeguard to ensure only non-identified information is shared per legal requirements<sup>4</sup>, and data is provided in a complete and timely manner to support timely and relevant research. Once this information is received, that's only the beginning. Substantial and complex processes are undertaken to convert this information into a form that is usable by industry, government, academia and others (see, for example, Attachment C, IQVIA Information Services Published Specifications for a summary description of these processes).

To be useful, data must be comprehensive, timely and valid. Research and precedent shows that databases need broad participation and protection to have integrity from a statistical perspective. By imposing patient authorization for the use of non-identified data, SB 703 excludes non-identified data from these databases by default. Requiring patients to authorize use of non-identified data (i.e., an opt-in approach) will corrupt research databases. For example, if an insufficient number of patients opt-in for a particular disease or treatment, the result might make detection of a disease or treatment pattern impossible. Also, the Mayo Clinic in Minnesota documented that statistical integrity can be undermined by "consent bias". The Mayo Clinic noted that those who consent to participate in research are qualitatively different from those who did not. Accordingly, any results from such studies could not be generalized to the population as a whole. In addition, the ability to identify and understand trends in healthcare requires stability in data sourcing over a period of years. Requiring patients to repeatedly opt-in as they interact with the healthcare system will destabilize data supply and undermine our ability to reliably perform these types of analyses. Time and again we've learned in health policymaking that enhancing existing protocols and programs – rather than radically upending established, proven methods – is less likely to disrupt patient care or stymie research and medical advances. SB 703 is a real threat to critical research to improve healthcare.

### **SB 703 Will Impose Substantial Burdens on Patients**

Patients routinely interact with multiple parts of the healthcare system. This is particularly true for older patients. Each interaction creates information about diagnosis, treatment, outcomes, costs and other aspects of healthcare. These information are held in a variety of systems by a variety of stakeholders. Information from many of these systems and stakeholders are used today to inform non-identified data collection and research. To collect enough information over a period of years, patient authorization will need to be solicited repeatedly to ensure SB 703 legal requirements are met (e.g., valid patient authorization) and research requirements are met (e.g., comprehensive, timely and valid data). Further, SB 703 anticipates the creation of a market in which patients will have a right to bargain for payment for these data and new mechanisms for obtaining patient authorization. Commercial research organizations will need to follow-up with patients repeatedly, directly and through providers and other stakeholders, until a sufficient number of patients have agreed to participate in

research. Forcing individuals to opt-in to use non-identified data in medical research and other important public health efforts will impose significant new burdens on patients.

### **SB 703 Interferes with HIPAA Protections**

Privacy laws around the world encourage the use of non-identified information for a wide range of purposes as an essential method to protect individual privacy. As HHS has noted:

The Privacy Rule was designed to protect individually identifiable health information through permitting only certain uses and disclosures of PHI provided by the Rule, or as authorized by the individual subject of the information. However, in recognition of the potential utility of health information even when it is not individually identifiable, §164.502(d) of the Privacy Rule permits a covered entity or its business associate to create information that is not individually identifiable by following the de-identification standard and implementation specifications in §164.514(a)-(b). These provisions allow the entity to use and disclose information that neither identifies nor provides a reasonable basis to identify an individual.<sup>5</sup>

Under HIPAA, the process of de-identification, by which identifiers are removed from the health information, mitigates privacy risks to individuals and thereby supports the secondary use of data described above. The increasing adoption of health information technologies in the United States accelerates their potential to facilitate beneficial studies that combine large, complex data sets from multiple sources. Large data sets of de-identified information can be used for innumerable purposes that are vital to improving the efficiency and effectiveness of health care delivery. As HHS stated in connection with the final HIPAA privacy rule: “We expressed the hope that covered entities, their business partners, and others would make greater use of de-identified health information than they do today, when it is sufficient for the purpose, and that such practice would reduce the burden and the confidentiality concerns that result from the use of individually identifiable information.”

Policymakers recognize that impediments to the creation and use of non-identified information discourages its use and creates incentives to significantly expand the use of individually identifiable information. SB 703 creates exactly the kinds of impediments that HHS and others sought to avoid with the HIPAA regulations. Burdens created by SB 703 include:

- Imposes burdens on patients to receive requests and related information to authorize the use of de-identified data for a wide variety of purposes
- Imposes burdens on healthcare providers and payers to communicate with patients to (i) educate patients about research opportunities that would benefit from the use of non-identified data, (ii) encourage patients to participate in commercial research, (iii) track and manage these authorizations to ensure non-identified data is released only when authorized
- Imposes burdens on commercial research organizations to ensure non-identified data has been authorized and a sufficient amount of data has been collected and maintained over a period of years to support a wide range of uses
- Imposes burdens on industry, government, academia and other users of commercial market research based on the use of non-identified data in order to encourage patients to authorize the use of non-identified data in research (e.g., providing explanations of the work to be performed and the benefits

to be obtained), and to identify and use alternative sources of information (to the extent these exist on a cost effective and timely basis) when commercial research organizations are unable to meet their research needs due to the unavailability of authorized non-identified data

As a consequence of the above, SB 703 will produce a substantial increase in the use of identifiable data and discourage use of de-identified data. This will erode privacy protection for patients, not improve it.

### **SB 703 Will Not Provide Any Financial Benefit to Patients**

No market exists for patients to sell their individual healthcare records to support large, complex datasets in support of the many uses described above. SB 703 and other legislative efforts won't create that market; it will only destroy existing research. The value paid to data sources for this data relates to their ability to provide large, consistent, timely, legally compliant data to support a wide range of uses. The value paid to companies like IQVIA relates to the insights researchers can obtain only after data collected from various sources is transformed through complex processes and turned into something usable. In small scale primary market research involving patients, participating patients receive compensation for their participation from commercial market research organizations (including IQVIA). However, an individual patient record has no value for research purposes in large scale analytics. Caregivers need individual patient information; researchers need information about populations. The value to patients, for all of us, is improvements to healthcare (e.g., improving patient outcomes, improving access to care, lowering costs).

### **SB 703 Does Not Add to Existing Prohibitions for Sale of Personal Health Information**

HIPAA has always prohibited the sale of an individual's protected health information ("PHI") without the proper authorization of the patient. More recently, as part of the final HITECH Omnibus Rule published in 2013, HHS clarified that a sale of PHI includes any circumstances where a covered entity or business associate (including downstream contractors and agents) "directly or indirectly receives remuneration from or on behalf of the recipient of the PHI in exchange for the PHI." As a result, SB 703 does not offer patients any incremental privacy protection.

### **IQVIA opposes SB 703 for all of the reasons stated above.**

We thank the Committee for this opportunity to comment. I hope the information contained in this letter informs your consideration of SB 703, and you will agree SB 703 should not become law. I also hope the Committee will recognize the substantial importance of the contributions made by commercial organizations using non-identified data to aid all healthcare stakeholders in the improvement of the healthcare system for the ultimate benefit of patients.

If I can be of any assistance by providing you with more details on any of the foregoing, or respond to questions, please let me know. More information regarding IQVIA may be found on our company's website at [www.iqvia.com](http://www.iqvia.com).

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Robert Hunkler". The signature is written in a cursive style with a long horizontal line extending to the right.

Robert J. Hunkler  
IQVIA Director, Government and Public Affairs

Attachment A – Representative list of media outlets reporting on a recent IQVIA Institute report  
Attachment B – Representative list of Federal government reports and releases citing IQVIA data  
Attachment C – IQVIA Information Services Published Specifications

## End Notes

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<sup>1</sup> See Advancing Academic Research, Bibliography of Published Papers and Presentations using IQVIA Information, July 2018, and Advancing Academic Research, Annotated Bibliography of Selected Research using IQVIA Information, July 2018, both available at <https://www.iqvia.com/institute/research-support>. See also published reports of the IQVIA Institute for Human Data Science on a wide range of topics available at <https://www.iqvia.com/institute>. Information available in IQVIA Institute reports are distributed without charge to inform public discourse and research, and are widely reported in the media for public benefit (see, for example, Attachment A with a list of media outlets reporting on a recent IQVIA Institute report). See also the amicus brief filed by Bloomberg L.P., The McGraw Hill Companies, Inc., Hearst Corporation, ProPublica, The Associated Press, The Reporters Committee for Freedom of the Press and the Texas Tribune in the U.S. Supreme Court case of *Sorrell v. IMS Health et al*, 564 U.S. 552 (2011). Also, the Federal government frequently cites IQVIA data in government reports and releases (see, for example, Attachment B, for a sample list of recent reports and releases).

<sup>2</sup> See Closing the Healthcare Gap, The Critical Role of Non-Identified Information, pages 11 – 23, December 2015, IMS Institute for Healthcare Informatics (n/k/a the IQVIA Institute for Human Data Science) available at <https://www.iqvia.com/institute>.

<sup>3</sup> See the amicus brief filed by HHS Secretary Dr. Louis W. Sullivan, HHS Secretary Tommy G. Thompson and the Healthcare Leadership Council in the U.S. Supreme Court case of *Sorrell v. IMS Health et al*, 564 U.S. 552 (2011).

<sup>4</sup> See HHS Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, November 26, 2012, available at <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>. See also “When De-Identifying Patient Information, Follow the HITRUST Framework, blog post by Sean Martin, HITRUST Independent Security Journalist, September 8, 2016, available at <https://blog.hitrustalliance.net/de-identifying-patient-information-follow-hitrust-framework/> and the HITRUST De-Identification Framework available at <https://hitrustalliance.net/de-identification/>.

<sup>5</sup> See HHS Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, page 6, November 26, 2012, available at <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>. See also the amicus brief filed by the Center for Democracy and Technology, the Genetic Alliance, the Pharmaceutical Care Management Association, Mark Frisse and Sara Rosenbaum in support of respondents petition for writ of certiorari to U.S. Supreme Court in the matter of *IMS Health, Inc. and Verispan LLC vs. Ayotte* on appeal from the United States Court of Appeals for the First Circuit, 550 F.3d 42 (2008).

## IQVIA Institute 2018 U.S. Medicines Report

### Major Media Coverage

Media Outlets – 68 total – major media listed below

1. [Associated Press \(1\)](#)
2. [Associated Press \(2\)](#)
3. [Axios](#)
4. [Becker's Hospital Review](#)
5. [Business Insider](#)
6. [Carroll County Times](#)
7. [CNBC](#)
8. [CNBC Squawk Box](#)
9. [CNBC Power Lunch](#)
10. [Daily Mail](#)
11. [Drug Store News](#)
12. [Financial Times \(1\)](#)
13. [Financial Times \(2\)](#)
14. [Forbes](#)
15. [Fortune](#)
16. [HealthDay](#)
17. [Health Populi](#)
18. [Kaiser Health News](#)
19. [KCBS-FM \(10:30 a.m. newscast\)](#)
20. [NY Daily News](#)
21. [New York Times](#)
22. [Nightly Business Report](#)
23. [Philly.com](#)
24. [STAT \(1\)](#)
25. [STAT \(2\)](#)
26. [The Africom](#)
27. [The Hill](#)
28. [UPI](#)
29. [Washington Post \(1\)](#)
30. [Washington Post \(2\)](#)
31. [Washington Examiner](#)
32. [CATO Institute Editorial](#)

NOTE: four tier-one media outlets ran two different stories of the report: AP, Financial Times, STAT, Washington Post

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**Representative List of Federal Government Reports and Releases Citing IQVIA Data**

#	Federal Government Agency	Title	Link to Publication (if available)
1	ASPE	Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures	<a href="https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf">https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf</a>
2	CDC	Notes from the Field: Pharmacy Needs After a Natural Disaster — Puerto Rico, September–October 2017	<a href="https://www.cdc.gov/mmwr/volumes/67/wr/mm6713a4.htm">https://www.cdc.gov/mmwr/volumes/67/wr/mm6713a4.htm</a>
3	CDC	Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015	<a href="https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm?s_cid=mm6626a4_w">https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm?s_cid=mm6626a4_w</a>
4	FDA	Trends and economic drivers for United States naloxone pricing, January 2006 to February 2017.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/29914719">https://www.ncbi.nlm.nih.gov/pubmed/29914719</a>
5	FDA	New Opioid Analgesic Approvals and Outpatient Utilization of Opioid Analgesics in the United States, 1997 through 2015.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/29557812">https://www.ncbi.nlm.nih.gov/pubmed/29557812</a>
6	FDA	FDA warns about rare occurrences of a serious infection of the genital area with SGLT2 inhibitors for diabetes	<a href="https://www.fda.gov/Drugs/DrugSafety/ucm617360.htm">https://www.fda.gov/Drugs/DrugSafety/ucm617360.htm</a>
7	FDA	Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM628319.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM628319.pdf</a>
8	FDA	Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM625472.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM625472.pdf</a>
9	FDA	Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM615313.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/UCM615313.pdf</a>
10	CMS	National Health Expenditures	<a href="https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html">https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html</a>
11	FDA	Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM611485.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM611485.pdf</a>

**Representative List of Federal Government Reports and Releases Citing IQVIA Data**

#	Federal Government Agency	Title	Link to Publication (if available)
12	FDA	Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)	<a href="https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm608100.htm">https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm608100.htm</a>
13	FDA	Joint Meeting of the Arthritis Advisory Committee (AAC) and Drug Safety and Risk Management Advisory Committee (DSaRM)	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM605207.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM605207.pdf</a>
14	FDA	Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM596199.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM596199.pdf</a>
15	RMPDC	Pediatric Suspected Suicide Exposures Involving Prescription Stimulants Are Increasing Faster than Stimulant Prescriptions	<a href="https://www.radars.org/system/publications/20182Q%20QTR.pdf">https://www.radars.org/system/publications/20182Q%20QTR.pdf</a>
16	RMPDC	Causal inference for evaluating prescription opioid abuse using trend-in-trend design	<a href="https://onlinelibrary.wiley.com/doi/epdf/10.1002/pds.4736">https://onlinelibrary.wiley.com/doi/epdf/10.1002/pds.4736</a>
17	FDA	Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC)	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM602417.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM602417.pdf</a>
18	RMPDC	Consistency Between Opioid-Related Mortality Trends Derived From Poison Center and National Vital Statistics System	<a href="https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2018.304728">https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2018.304728</a>
19	CDC	HIV Preexposure Prophylaxis, by Race and Ethnicity — United States, 2014 - 2016	<a href="https://stacks.cdc.gov/view/cdc/59999">https://stacks.cdc.gov/view/cdc/59999</a>
20	FDA	Advancing Toward the Goal of Global Approval for Generic Drugs: FDA Proposes Critical First Steps to Harmonize the Global Scientific and Technical Standards for Generic Drugs	<a href="https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm623665.htm">https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm623665.htm</a>
21	FDA	Drug availability adjustments in population-based studies of prescription opioid abuse	<a href="https://www.ncbi.nlm.nih.gov/pubmed/28000295">https://www.ncbi.nlm.nih.gov/pubmed/28000295</a>

**Representative List of Federal Government Reports and Releases Citing IQVIA Data**

#	Federal Government Agency	Title	Link to Publication (if available)
22	FDA	Joint Meeting of the Psychopharmacologic Drugs Advisory Committee & Drug Safety and Risk Management Advisory Committee	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM629501.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM629501.pdf</a>
23	FDA	Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee Meeting	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM630970.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM630970.pdf</a>
24	FDA	Meeting of the Anesthetic and Analgesic Drugs Products Advisory Committee	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM624042.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM624042.pdf</a>
25	FDA	Preliminary Regulatory Impact Analysis Initial Regulatory Flexibility Analysis Unfunded Mandates Reform Act Analysis	<a href="https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM628697.pdf">https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM628697.pdf</a>
26	FDA	Trends of Outpatient Prescription Drug Utilization in US Children, 2002-2010	<a href="https://www.ncbi.nlm.nih.gov/pubmed/22711728">https://www.ncbi.nlm.nih.gov/pubmed/22711728</a>
27	CDC	County-Level Opioid Prescribing in the United States, 2015 and 2017	<a href="https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2723623">https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2723623</a>
28	FDA	Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee Meeting	<a href="https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM629362.pdf">https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM629362.pdf</a>
29	FDA	Addressing Opioids: The FDA Response to Challenges in Public Health	<a href="https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM628246.pdf">https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM628246.pdf</a>
30	FDA	FDA Update: 2018	<a href="https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM609075.pdf">https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM609075.pdf</a>

## **IQVIA Information Services Published Specifications**

(January 2018)

### **Introduction**

IQVIA is a leading provider of information and technology services for the healthcare industry, covering markets in 100+ countries around the world. A leader for more than 60 years, we blend industry expertise and advanced technology to deliver in-depth analytics on healthcare dynamics. We have one of the largest and most comprehensive collections of healthcare information in the world, spanning sales, prescription and promotional data, medical claims, electronic medical records and social media. We continuously innovate to keep pace with a global healthcare environment that is highly dynamic and increasingly complex and interdependent.

IQVIA information services represent a wide array of offerings reporting on various aspects of medicines and health care in countries around the world. In market research and other methods of estimating activity in the world, numbers are prepared using judgment and skill, not simply arithmetic. Further, information is initially input at the source by thousands of people, often manually, in thousands of organizations. Further still, this information is often gathered from IT systems that were designed for and serve a purpose other than measuring market activity (e.g., electronic medical records, pharmacy systems, payment systems), so the design of the data fields and the choices available to populate those fields are not intended to meet the needs of IQVIA's clients. Each of these characteristics of the underlying components of market measures has an impact on the ultimate accuracy and meaning of the final numbers.

Although there is an inclination to view numerical data as fact, IQVIA information represents an estimate of measured activity and should be treated accordingly. To use it effectively, it is important to have a sufficient understanding of how the information is sourced, processed, standardized, produced and reported. Further, proper practice involves the use of IQVIA information in combination with other information (e.g., knowledge based on skills and experience, other information and observations in the marketplace) to make decisions. To help customers obtain the most value from IQVIA information services and use the information in a manner that is consistent with its specifications, this document provides an overview of the processes employed by IQVIA to produce and report these estimates, and a list of appropriate practices in the use of such information.

We prepared this document to help you use IQVIA information services more effectively. This document provides an overview of methods we employ to source, collect, cleanse, bridge, edit and organize information. We then apply some combination of sophisticated computer processing, statistical projections, advanced analytics, forecasting methodologies and our skills and experience to provide you with answers, insights and tools. We don't use every method described in this document in every one of our hundreds of offerings; we use commercially reasonable efforts to employ many of these in each of our offerings commensurate with the nature and cost of the service

in order to provide our customers with the most comprehensive and effective measures of pharmaceutical and health care markets in the world.

## **IQVIA Processes**

### Data Sourcing

IQVIA collects information from a wide variety of sources. Some of that information is collected through surveys, which may be completed by respondents as the activity occurs or completed later based on review of records or an individual's recollection, and which may be completed by the person engaged in the activity (e.g., provider) or someone else at their location (e.g., nurse, technician, administrative staff). Other information may be gathered from business records based upon fields of information that an organization is willing to provide, with the information gathered as a by-product of the business process which produces it (i.e., health records and payment systems are designed for a particular purpose, so data collection for other purposes is a secondary use of the information). Although IQVIA seeks accurate, complete and timely information from these sources, the information is frequently provided with limited assurances regarding quality and timeliness. In addition, IQVIA frequently uses pre-defined formats for responses, financial incentives, feedback reports, notification requirements for changes in data or systems, retention of back-up copies of data at the source, record layouts, contractual undertakings to avoid the blocking of data at the request of others and other approaches to encourage the delivery of high quality and timely data provided by these sources, commensurate with the nature of the data collection activity (e.g., approaches appropriate for a physician completing a monthly market research survey versus a large commercial organization providing gigabytes of transactional information on a daily basis).

### Data Receipt

IQVIA takes care to establish reasonable methods of delivery for information from hundreds of thousands of sources to support the timely and secure delivery of data to IQVIA. Following receipt of data from its sources, IQVIA employs a variety of initial quality control checks and processes to ensure data has been properly delivered to IQVIA. IQVIA also contacts sources if data is not received on a timely, complete or accurate basis as a result of these initial quality control checks (to the extent detectable). Data record statistics (e.g., record counts) accompany data delivery to ensure data shipment records match data receipt records. Further, IQVIA maintains various metrics and parameters regarding the characteristics of each individual data file received and promptly investigates discrepancies or unusual variances identified through its automated quality control processes. Data suppliers are frequently contacted to assist with resolution of these issues. IQVIA promptly performs manual adjustments to data based on acknowledgement by supplier of file issues, allowing for prompt correction of many issues prior to the start of database creation and the report production schedule. IQVIA maintains readily available back-up copies of incoming data sets in conjunction with report production in the event data processing issues are identified, providing IQVIA with the ability to rapidly re-process data.

### Data Editing / Validation

In addition to the processes referenced above, IQVIA has invested significantly in the development of proprietary data cleansing, editing, and other sophisticated tools to find data issues and provide visibility to any issues as they become apparent. The benefit for IQVIA clients is our ability to proactively identify situations that may exceed standard variances. Although these quality control

checks and processes will vary by data type, examples include: (a) examination of the information in various fields for each transaction to ensure the field contains a valid value, (b) maintenance of various metrics and established variances regarding the characteristics of each transaction (e.g., days' supply of product, quantity by product), (c) maintenance of various metrics and established variances regarding the characteristics of the source, (d) analysis of historical distribution, prescribing, dispensing or other applicable patterns of measured activity, and (e) analysis of historical reporting patterns. If unusual variances are encountered, IQVIA investigates the situation or takes other appropriate actions, often working closely with the sources of the data to determine if the variances are acceptable or require corrections. Data exceeding acceptable variance ranges will not be utilized unless verified. Despite all these processes and procedures to capture data quality errors upon receipt, it is impossible to capture all errors that might exist within the boundaries of the acceptable variance levels and therefore can be a source of variability within IQVIA information.

### Reference Files

To standardize data received from a wide variety of sources and allow for alignment of the data prior to projection or aggregation, IQVIA develops and maintains reference files for various types of information, including medicines, diagnoses, treatment modalities, distribution centers, health care offices, integrated health networks, insurance plans and data classification schemes. IQVIA employs a number of processes to maintain the quality of these reference files, including: (a) acquisition and integration of a significant number of reference file updates received from a variety of sources, (b) manual data validation to confirm the existence and accuracy of the reference information, (c) maintenance of linkages between IQVIA standard identifiers and industry standard identifiers, and (d) investigations of reported data discrepancies.

### Data Quality Bridging

IQVIA receives data relating to tens of millions of transactions each week. To standardize data for each transaction received from a wide variety of sources (e.g., suppliers frequently use their own proprietary reference numbers) and allow for alignment of the data prior to projection or aggregation, IQVIA links key record variables to IQVIA standard reference files as applicable for the particular service. As changes occur in the marketplace (e.g., new product or a new form, pack or strength of an existing product), and these changes are reported to IQVIA, IQVIA works quickly to map these changes in data arriving from sources to IQVIA's standard reference files. IQVIA employs a number of processes to maintain the quality and results of the bridging process, including: (a) development and maintenance of algorithms for the matching / linking of supplier reference numbers with IQVIA reference files, (b) identification of new, deleted or modified supplier reference numbers for purposes of promptly linking these to IQVIA reference files, and (c) annual bridge validation for key products.

### Database Management

When data has successfully passed through the processes referenced above, it is then added to the applicable IQVIA database. In connection with the movement of the information to these databases, IQVIA employs additional quality control processes, including: (a) IQVIA examines the data to ensure data file statistics match as data moves from one process to another process (e.g., number of records), and (b) all programming logic, statistical methodologies and other computer algorithms applied to the data to create these databases and the applicable reports pass through rigorous development and testing methodologies prior to implementation in the production environment.

### Projection Methodologies

Most IQVIA offerings are derived from the use of statistically representative samples, not a census of activity. More than one hundred statisticians support the development of sample designs and projection methodologies to estimate activities to achieve a high degree of accuracy on a cost effective basis. IQVIA frequently employs higher coverage rates than statistically necessary for many of its offerings to properly reflect key aspects of the pharmaceutical and health care markets. Nevertheless, sample designs, projection methodologies and coverage rates all have an impact on the degree of accuracy of IQVIA information. Information regarding confidence intervals and other measures of accuracy are available to IQVIA customers.

### Imputation Methodologies & Temporary Replacement Data

On occasion, IQVIA employs data imputation methodologies that allow IQVIA for a short period of time to impute data for a supplier or facility location if data supply is interrupted or severe data quality issues are uncovered. By using imputation methodologies for missing data, analysis has shown that IQVIA offerings are more accurate and not prone to trending spikes caused by issues in the data flow process (i.e. enabling analysis of true trends based on marketplace activities).

### Client Report Creation

Certain IQVIA reports involve customization based on customer supplied report parameters (e.g., market definitions and geographic reporting specifications). IQVIA employs methods to verify the customer supplied parameters and ensure these have been properly entered into IQVIA report production systems. These customized reports undergo validation procedures in an effort to ensure these parameters have been applied correctly.

### Data Availability

IQVIA provides the most comprehensive set of market measures in the world. However, numerous factors can potentially impact the acquisition and/or usability of such information, including: (a) contractual restrictions from sources of data on the use, types of customers, applications and publication of information, (b) legal restrictions, (c) data origination (e.g., data entry errors; system coding issues), (d) data suppliers (e.g., variations in processing), (e) market events, and (f) natural disasters. IQVIA works hard to avoid data variability in these circumstances and find reasonable solutions to account for the impact of these issues on IQVIA information.

## **Appropriate Uses of IQVIA Information**

Applications using IQVIA information should be designed to accommodate the unique characteristics of the information. As noted above, there are a multitude of people, sources, systems, laws, methodologies and other issues that can impact the quality and nature of this information. Users of IQVIA information should design applications that leverage strengths and minimize weaknesses of such information to avoid application errors or flawed decision-making. These design considerations include:

- Use confidence intervals: Confidence intervals are expressed in terms of a range of values around the sample-based estimate associated with a particular probability, or level of confidence, that the true value is contained within that range.

- Account for normal variations in trends over historic periods of time: Incorporate tolerance ranges into analysis to identify data points which fall outside of normal variations. Look for industry events or other known causes which might account for the unexpected deviation. Examples might include significant weather events, product manufacturing issues affecting inventory, etc.
- Use similar historic periods when using data: Apply historical trends in tandem when viewing market share for a reasonability test (e.g., holiday periods, seasonality).
- Manage expectations: Set expectations within your organization and with your vendors so normal variation is understood to avoid incorrect decision-making, poorly designed applications or a loss of confidence in IQVIA information.
- Vendor selection: Be sure each of your vendors working with IQVIA data understands the related healthcare markets and the underlying characteristics associated with the data.
- Anticipate greater variability for low volume or more granular estimates: Recognize that using data on low volume products or extracting data of increasing granularity (e.g. smaller groups of prescribers or smaller geographic areas) increases the variability of the data estimations.
- Market share versus volume: Use market share for more consistency than volume. While individual product volume estimations are desirable to report product sales trends, those estimations are subject to the variability noted in this document. By viewing product trends in the context of an entire market (market shares), whereby each product is estimated with a similar degree of variability, the resulting calculations may improve the overall consistency of the market measure.

## Summary

IQVIA information is gathered from a wide variety of data sources using many different methods. The data are complex, non-standard, and can be inherently variable when submitted to IQVIA. We use sophisticated tools and business practices to gather, validate, standardize, project, and report such information. As such, IQVIA information represents an estimate of measured activity and should be treated accordingly. We encourage customers to apply the considerations provided above, and to use the tools and guidance materials provided from IQVIA in order to use IQVIA information effectively.