Clinical Trial Transparency: The FDA Should and Can Do More

Amy Kapczynski and Jeanie Kim

In recent years, the scientific community and regulators have increasingly recognized the value of data transparency in clinical research. Adding to this momentum, the *Blueprint for Transparency at the FDA* calls upon the U.S. Food and Drug Administration to act as a key intermediary for sharing clinical trial data. We strongly support the *Blueprint*'s recommendations for the FDA to proactively release substantially more pre-market and post-market clinical trial data submitted by companies. The FDA is in a particularly good position to facilitate public disclosure of data. Tasked with comprehensively regulating the drugs, devices, and biologics on the U.S. market, the agency has access to a wealth of clinical trial data and receives more data than its European counterpart.[1] Notably, the recently appointed FDA Commissioner Scott Gottlieb has expressed his support for data transparency, acknowledging that the agency should leverage its regulatory authority to release data in the public's interest.[2]

In this brief commentary, we show that the FDA has the legal authority to share much more clinical trial data that it currently does. We also show that the primary existing route for obtaining such data from the FDA — individual requests under the Freedom of Information Act (FOIA) — can be used to obtain important categories of data, particularly summary data and metadata. But FOIA cannot substitute for a comprehensive data sharing system that prioritizes public health. The FOIA approach can take years, often requires litigation, and will be piecemeal and reactive in nature. A more proactive approach to the release of data would allow the FDA to set priorities and to build a platform for data sharing that maximizes the benefits for patients and the research community. Such a platform could also, when appropriate, craft data use agreements that protect patient privacy while promoting research integrity and transparency.

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The FDA Should Proactively Share More Clinical Trial Data

The FDA's core public health mission is to ensure that medicines are safe and effective for their intended uses — a task primarily accomplished by evaluating the rigor and sufficiency of the evidence submitted by companies. By sharing data from clinical studies, the FDA can improve the evidence base that informs patients, providers, and payers, and help protect the integrity of the clinical research enterprise. In 2015, the Institute of Medicine (IoM) released one of the most comprehensive reports in support of sharing data from clinical trials.[3] The report defines three categories of clinical trial data: "individual participant data" (i.e., raw data and the analyzable data set); metadata, or 'data about the data' (e.g., protocol, statistical analysis plan, and analytic code); and summary-level data (e.g., summary-level results posted on registries, lay summaries, publications, and [clinical study reports (CSRs) submitted for regulatory review]).".[4]

As the report emphasizes, transparency for each category offers distinct benefits. By sharing summary

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results, the FDA can "help[] protect against publication bias."[5] Many clinical trial results that are submitted for regulatory review are unpublished or differ significantly from the results that are selectively reported in journals.[6] Disseminating summary data ensures that patients and the research community have access to all trial results that are relevant for clinical care, and not just the positive or favorable outcomes.[7] Furthermore, the FDA receives detailed summaries in CSRs that contain far more information than what is found in publications.[8] Making CSRs publicly available "allows for better understanding of regulatory decisions and facilitates the use of analyzable data set."[9] Clinical trial protocols should also be shared because they provide context for understanding published data, as well as any summary data and analyzable data that are shared.[10]

The FDA is reportedly the only regulator that routinely obtains analyzable data sets.[11] The sharing of such data sets, accompanied by study protocols and summary data, to qualified independent researchers "allows for reanalysis, meta-analysis, and scientific discovery through hypothesis generation."[12] Secondary researchers can help identify issues that may have been missed by regulators or understudied or buried by companies.[13]

The FDA Can Proactively Share More Clinical Trial Data

Despite the potential benefits, the FDA does not proactively share most of the clinical trial data in its possession in any comprehensive fashion. Congress has set forth baseline disclosure requirements for the FDA as well as some confidentiality obligations. However, much of the data submitted to the FDA falls somewhere between these two poles, giving the FDA discretion to determine what should be made available in the public's interest and what should be kept confidential.

Federal agencies generally have the authority to release information to the public if the release is not otherwise forbidden by law. FOIA, enacted in 1966, embodies this core presumption in favor of transparency.[14] In passing FOIA, Congress evinced "a general philosophy of full agency disclosure unless information is exempted under clearly delineated statutory language."[15] Moreover, while FOIA provides several exemptions, including Exemption 4 for "confidential commercial information" (CCI) and Exemption 6 for personal privacy,[16] courts have found that Congress did not intend for the exemptions themselves to create absolute bars to disclosure.[17] Rather, the exemptions are "workable standards" designed to *permit* an agency to withhold certain information without limiting its discretion to disclose that information either proactively or in response to a FOIA request.[18] In general, even if information falls under an exemption, agencies have the discretion to release it if there is a compelling public interest in disclosure related to the agency's activities and and if the disclosure is not barred by another law.[19]

The FDA has yet to fully exert its discretion to release much of the summary data, metadata, and individual participant data (IPD) in its possession. To do so, the FDA would first have to recognize that many types of clinical trial data can be shared without genuine risks to patient privacy. Summary-level trial results, CSRs, and study protocols typically contain no patient-specific information or can be easily redacted to remove patient identifiers.[20] Analyzable data sets present more complex privacy concerns, and some may be difficult to fully de-identify without rendering them useless for secondary analyses.[21] However, emerging protocols for de-identification make it possible to sufficiently anonymize certain analyzable IPD so that the risk of re-identification is very small.[22] Agencies have the discretion to weigh legitimate personal privacy concerns against the public interest in disclosure and to share data if the privacy risks are minimal in relation to a public benefit.[23] The FDA is well positioned to consider the privacy risks and public health benefits associated with sharing different types of clinical trial data, and the FDA and the U.S. Department of Health and Human Services have both signaled interest in exploring ways to share de-identified IPD from clinical trials submitted for regulatory review.[24]

While agencies have less discretion with respect to CCI because of overlapping nondisclosure laws that prohibit federal employees from unauthorized release of commercial or financial data, they are still entitled to substantial deference to determine the initial threshold question of what constitutes CCI.[25] This is a critical point for the FDA when considering various types of clinical trial data. Much of the clinical trial data that researchers need for meta-analyses and secondary analyses simply is not CCI, or can be redacted to address any CCI concerns. The IoM Report describes how commercially sensitive information that reflects a company's business strategies and clinical development processes can be separated from analyzable data that are more objectively collected and tabulated.[26] For example, CSRs, which contain manufacturing formulas or clinical trial site information, can be redacted to address legitimate CCI issues. Courts have also rejected CCI arguments for certain types of clinical research data, including postmarket study protocols and raw safety data, where the claims of competitive harm are negligible or vague.[27]

The FDA's lack of proactive disclosure is particularly problematic where data relevant to drug safety

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is concerned, because Congress has expressed in clear terms its intention that the agency disclose data relevant to that question. The Food and Drug Administration and Amendments Act (FDAAA) instructs the FDA to maintain a website that provides patients and providers with better access to safety information about drugs and biologics.[28] The FDA must post the most recent FDA-issued safety alerts, warning letters, links to the trial registry and results, and "*other material* determined appropriate by the [agency]."[29] To fulfil its obligation to release "other material" pertinent to patient safety, the FDA should routinely release at least data like CSRs, summary results, full protocols, and analyzable datasets that can be de-identified.[30] These data are pertinent to drug safety, and to the balancing of risks against clinical benefits for particular indications, and can help patients, providers, and the research community fully understand the safety profile of drugs and devices.

Congress has also pressed the FDA to be more forthcoming and has urged the agency to incorporate broader transparency policies for the benefit of the public. Congress has done this not only in congressional hearings,[31] but also through specific laws, such as statutory provisions that mandate the release of "action packages" — the FDA's summaries of all safety and effectiveness data in its possession — for every approved new drug or biologic.[32] These disclosure requirements are intended to address the discrepancies between the comprehensive information that the FDA possesses and the selective information that is publicly available, which in many cases have led to widespread patient harms.[33] In order to further bridge information gaps and increase the value of clinical research data, the FDA should revisit whether various types of data legitimately fall under FOIA exemptions, particularly Exemptions 4 and 6, and affirm the scientific and public health value of data sharing. This is particularly appropriate where, as in the case of data that sheds light on drug safety, Congress has expressed its view that an interest is especially compelling.

Leveraging FOIA to Obtain Clinical Trial Data from FDA: A Partial Solution

When faced with requests for particular clinical trial data, the FDA has in fact released many types of clinical trial data, implicitly conceding that such disclosures do not raise commercial confidentiality or personal privacy concerns. We recently used FOIA to seek access to clinical trial data for Gilead's blockbuster Hepatitis C drugs, sofosbuvir (Sovaldi) and ledipasvir/sofosbuvir (Harvoni).[34] Although it took two years of litigation, the FDA has now released tens of thousands of pages of summary data and metadata, including safety and effectiveness summary-level data, full protocols that include analysis plans and amendments, and CSRs. The agency redacted very little — for example, select information about ingredients and manufacturing information that was commercially confidential, and participant contact information that implicated privacy. Notably, Gilead had intervened in the case early on, thereby presumably consenting to all data disclosures and implicitly admitting that there are few CCI and privacy concerns relevant to these categories of data, and that those that exist can be addressed through simple redactions.

Our suit did not resolve the extent to which FOIA can be used to access IPD and analyzable datasets. The orientation of FOIA — a disclosure law designed for all types of governmental information — may sometimes make it a blunt tool for these purposes. FOIA rests on a philosophy of broad public dissemination and equal

> Until the FDA proactively releases data on a routine basis, individual FOIA requests are the only mechanism to obtain data that the agency does not release. Our experience with FOIA shows that the process can be a very powerful tool for obtaining clinical trial data, at least of the summary and metadata variety, but that FOIA also has important limits. First, valid FOIA requests can go unfulfilled without the aid of a lawyer to take the agency to court for its failure to timely respond. Second, even when successful, the process is slow. Requests for clinical trial data are likely to be put in the slower "complex" queue because of the high volume and complexity of the data as well as the need for redactions, and so typically it will take years to resolve.

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access to information. Once one entity receives information under FOIA, the public as a whole is presumed to have the right to access the same material.[35] Courts have historically found that selective or conditional data disclosure arrangements are not consistent with the purpose of FOIA.[36] However, such arrangements — like data use agreements with confidentiality provisions — may, depending on the circumstances, be the best means of sharing analyzable data to secondary researchers at a reasonable cost, while also protecting patient privacy and commercial interests.[37]

Until the FDA proactively releases data on a routine basis, individual FOIA requests are the only mechanism to obtain data that the agency does not release. Our experience with FOIA shows that the process can be a very powerful tool for obtaining clinical trial data, at least of the summary and metadata variety, but that FOIA also has important limits. First, valid FOIA requests can go unfulfilled without the aid of a lawyer to take the agency to court for its failure to timely respond. Second, even when successful, the process is slow. Requests for clinical trial data are likely to be put in the slower "complex" queue because of the high volume and complexity of the data as well as the need for redactions, and so typically it will take years to resolve.[38] Despite the hundreds of hours of legal assistance, it took us nearly two years to begin receiving data pursuant to our FOIA request.[39] The process can be slow even where a research question is exceptionally urgent, and the FDA grants "expedited processing." In 2014 and 2015, the FDA completed two requests that were granted expedited processing; it took the agency 693 days and 862 days respectively to finish document production.[40]

FOIA is also better suited to individual requests for specific data than for systematic release of data of scientific and public health importance. Production of data generally occurs piecemeal for practical reasons, and recipients of data may, but are not obliged to, release the data they receive to others. Proactive release of data by the FDA would be preferable to the current reactive approach for many reasons. It would allow the agency to ensure that researchers have equitable access to data. The agency could also — and should — prioritize, releasing first those categories of information that are both important and readily redactable, such as CSRs and protocols for widely prescribed drugs. Proactive release would also allow the agency — possibly with additional appropriations — to create a dedicated and centralized platform, alone or in conjunction with other entities, that would give investigators with legitimate scientific and public health inquiries access to redacted and de-identified datasets, similar to the National Institutes of Health's database for biomedical and clinical research.[41] The FDA could also design optimal conditions for data sharing. For an example, where appropriate, the agency could implement data use agreements that prohibit improper uses of shared data or further promote transparency by requiring that results of studies using the data be publicly shared.[42]

By proactively sharing data, the FDA can address the limitations of FOIA and create data sharing policies that promote the health and safety of all Americans. The public interest in data disclosure is more urgent and compelling now than when the FDA first formulated its disclosure policies. With modern advances in data generation and analyses, there is an even greater potential for data sharing to enhance and accelerate medical knowledge. By proactively sharing data, the FDA can better fulfill its responsibilities to patients and public health.

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3. IoM Report, *supra* note 1.
4. *Id.*, at 7 (emphasis added).
5. *Id.*
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7. IoM Report, *supra* note 1, at 32; see, e.g., D. Eyding, M. Lelgemann, U. Grouven, et al., "Reboxetine for Acute Treatment of Major Depression: Systematic Review and Meta-Analysis of Published and Unpublished Placebo and Selective Serotonin Reuptake Inhibitor Controlled Trials," *BMJ* 341, no. c4737 (2010), *available at* <http://www.bmj.com/content/341/bmj.c4737> (last visited November 1, 2017).
8. *Id.*, at 110.
9. IoM Report, *supra* note 1, at 111.
10. *Id.*, at 100, 102-103, 105.

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11. *Id*., at 68-69.
12. *Id*., at 7.
13. *Id*., at 99 ("The full analyzable data set is generally the most useful set of data to share from a trial, with large and likely important benefits to science and society"); see, e.g., S. E. Nissen and K. Wolski, "Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes," *New England Journal of Medicine* 356, no. 24 (2007): 2457-2471; Group WARNWDS, "The Effect of Dosing Regimens on the Antimalarial Efficacy of Dihydroartemisinin-Piperaquine: A Pooled Analysis of Individual Patient Data," *PLOS Medicine* 10, no. 12 (2013): e1001564.
14. 5 U.S.C. § 552 (2017).
15. *U.S. Dep't of the Air Force v. Rose*, 425 U.S. 352, 360-61 (1976) (quoting S.Rep. No. 813, 89th Cong., 1st Sess., 3 (1965)).
16. 5 U.S.C. § 552(b)(4) & (b)(6).
17. *Chrysler Corp. v. Brown*, 441 U.S. 281, 293 (1979).
18. *Chrysler Corp*., 441 U.S. at 294 (quoting H. R.Rep. No. 1497, 89th Cong., 2d Sess., 2, 5 (1966)); see also *Dep't of the Air Force v. Rose*, 425 U.S. at 361 (The FOIA exemptions "do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act," and thus, they must be "narrowly construed").
19. *CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1134 n.1 (D.C. Cir. 1987) ("The agency's decision to release the data normally will be grounded either in its view that none of the FOIA exemptions applies, and thus that disclosure is mandatory, or in its belief that release is justified in the exercise of its discretion, even though the data fall within one or more of the statutory exemptions."); see *Jurewicz v. U.S. Dep't of Agriculture*, 741 F.3d 1326, 1332 (D.C. Cir. 2014) (finding that a substantial privacy interest "must be balanced against any public interest in disclosure ... [to the extent that] disclosure of the information sought would ... let citizens know 'what their government is up to.'") (quoting *U.S. Dep't of Def. v. Fed. Labor Relations Auth*., 510 U.S. 487, 497 (1994)). Where CCI is concerned, however, the balancing of public interests may be inappropriate because the category overlaps with other laws that flatly forbid agencies from making unauthorized disclosures of commercial data. *CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1140 (D.C. Cir. 1987) (finding that 18 U.S.C. § 1905 "appears to cover practically any commercial or financial data collected by any federal employee" such that information that falls under Exemption 4 is barred from disclosure unless otherwise authorized). But, the U.S. Court of Appeals for the Seventh Circuit has suggested a different interpretation — that § 1905 was intended to protect a narrower category of information than Exemption 4, thereby preserving some agency discretion to disclose information that falls within Exemption 4. *Gen. Elec. Co. v. U.S. Nuclear Regulatory Comm'n*, 750 F.2d 1394, 1402 (7th Cir. 1984) ("Exemption 4 is broadly worded, and it is hard to believe that Congress wanted seekers after information to stub their toes on a rather obscure criminal statute almost certainly designed to protect that narrower category of trade secrets ... whose disclosure could be devastating to the owners and not just harmful").
20. IoM Report, *supra* note 1, at 102-103, 108-109, 111.
21. M. M. Mello et al., "Preparing for Responsible Sharing of Clinical Trial Data," *N. Engl. J. Med.* 369 (2013): 1651-1658.
22. IoM Report, *supra* note 1, at 208-213 (Appendix B) (referring to the de-identification methods provided in the Privacy Rule of the U.S. Health Insurance Portability and Accountability Act (HIPAA) as "a good launching point for examining best practices" for sharing analyzable clinical trial data).
23. *U.S. Dep't of the Air Force v. Rose*, 425 U.S. at 372 (finding that Exemption 6 requires a balancing of the individual's right to privacy against the public's right to disclosure under FOIA); *Consumers' Checkbook Ctr. for the Study of Servs. v. U.S. Dep't of Health and Human Servs*., 554 F.3d 1046, 1057 (D.C. Cir. 2009) (stating that FOIA's "presumption favoring disclosure ... is at its zenith under Exemption 6") (quoting *Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 37 (D.C. Cir. 2002)); see also *Jurewicz v. U.S. Dep't of Agriculture*, 741 F.3d 1326, 1331-34 (D.C. Cir. 2014) (in reverse-FOIA case, deferring to an agency's decision that that any personal privacy concerns are minimum and outweighed by the public's interest "in assessing whether the [agency] is fulfilling its statutory mandate" and "gaug[ing] the effectiveness of [agency] inspections by comparing data ... with publicly available inspection reports").
24. In 2013, the FDA proposed sharing de-identified analyzable safety and efficacy datasets, acknowledging that such data "have tremendous potential to ... provide new opportunities for innovation in medical product development." "Availability of Masked & Deidentified Non-Summary Safety & Efficacy; Request for Comments," 78 *Federal Register* 33421, 33422 (June 3, 2013). More recently, in 2016, the U.S. Department of Health and Human Services has expressed a willingness to explore whether *ClinicalTrials.gov* can "provide[ ] the scaffolding on which individual participant data ... (the next frontier in transparency) and other trial "meta-data" can be organized in the future," and the agency "anticipate[s] that *ClinicalTrials.gov* can be used in the future to catalyze IPD sharing." "Clinical Trials Registration and Results Submission Final Rule," 81 *Federal Register* 64,981, 64,988, 64,991 (Sept. 21, 2016) (codified at 42 C.F.R. Pt. 11).
25. *CNA Fin. Corp. v. Donovan*, 830 F.2d 1132 (D.C. Cir. 1987) (finding that 18 U.S.C. § 1905 is "co-extensive" with FOIA's Exemption 4 for CCI, but holding that the agency's determination that the information at issue is not CCI to be reasonable); see also *Jurewicz v. U.S. Dep't of Agriculture*, 741 F.3d 1326, 1331 (D.C. Cir. 2014) (Exemption 4 "requires a showing of both actual competition and a likelihood of substantial competitive injury ... [and the court] will generally defer to the agency's predictive judgments as to the repercussions of disclosure") (internal quotations omitted).
26. IoM Report, *supra* note 1, at 259-60.
27. *Pub. Citizen Health Research Group v. U.S. Food and Drug Admin.*, 964 F. Supp. 413 (D.D.C. 1997) (ordering release of post-market study protocols after finding that disclosure would not result in competitive harm); *Pub. Citizen Health Research Group v. U.S. Food and Drug Admin.*, 2000 WL 34262802 (D.D.C. 2000) (holding that CCI claims were vague and ordered release of underlying raw data to a graph with safety information given to an advisory committee); see also *Teich v. U.S. Food and Drug Admin.*, 751 F. Supp. 243, 255 (D.D.C. 1990) (rejecting FDA's argument that the requested animal studies and consumer complaints are CCI and found that any competitive harm is "negligible").
28. 21 U.S.C. § 355(r); FDAAA § 915.
29. 21 U.S.C. § 355(r)(2)(B) (emphasis added).
30. The FDA does release downloadable analyzable datasets on a quarterly basis containing de-identified synopses of individual adverse event reports that are collected in the FDA Adverse Event Reporting System (FAERS) database, *available at* <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm082193.htm> (last visited November 2, 2017).
31. U.S. Cong. House. Committee on Energy and Commerce. Subcomittee on Oversight and Investigations, *Hearing on Publication and Disclosure Issues in Anti-Depressant Pediatric Clinical Trials September 9, 2004*. 108th Cong. 2d sess.: at 27, 35-37, 41, *available at* <https://www.gpo.gov/fdsys/pkg/CHRG-108hhrg96094/html/CHRG-108hhrg96094.htm> (last visited November 2 2017) (Reps. Deutsch, Bass, and DeGette questioning Dr. Janet Woodcock, then acting Deputy Commissioner of Operations, why the FDA disclosed only the summaries of trials but "not the actual clinical trials" and what Congress can do to "clarify what [the FDA] believe[s] to be the deficiencies in the law that would allow ... full disclosure of all these trials.").
32. 21 U.S.C. § 355(l)(2); FDAAA § 916.
33. House Committee on Energy and Commerce Committee Hearing, *supra* note 31; see also Complaint, *The People of the*

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State of New York v. GlaxoSmithKline, 401707/2004 (N.Y. Sup. Ct. June 2, 2004), *available at* <http://news.findlaw.com/wsj/docs/glaxo/nyagglaxo60204cmp.pdf> (last visited November 2, 2017).

34. *Treatment Action Group et al v. U.S. Food & Drug Admin.*, No. 15-cv-976 (VAB) (D. Conn. Sept. 20, 2016).
35. 5 U.S.C. § 552(a)(3) (all records requested under FOIA that are not exempt must be made "promptly available to any person"); *Dep't of Justice v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 771 (1989) (FOIA is "clearly intended ... to give any member of the public as much right to disclosure as one with a special interest") (quoting *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 149 (1975)).
36. See *Swan v. SEC*, 96 F.3d 498, 500 (D.C. Cir. 1996) ("Once records are released, nothing in FOIA prevents the requester from disclosing the information to anyone else. The statute contains no provisions requiring confidentiality agreements or similar conditions."); *Maricopa Audubon Soc. v. U.S. Forest Serv.*, 108 F.3d 1082, 1088–89 (9th Cir. 1997) (holding "that FOIA does not permit selective disclosure of information only to certain parties, and that once the information is disclosed . . . it must also be made available to all members of the public who request it.")
37. IoM Report, *supra* note 1, at 13 ("data use agreements are a promising vehicle for reducing ... risks and related disincentives for sharing clinical trial data).
38. 21 C.F.R. § 20.43(a) (permits each FDA department to establish multiple tracks for processing FOIA requests "based on the amount of work and/or time required for a request to be processed").
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40. U.S. Health and Human Services, *HHS Fiscal Year 2015 Freedom of Information Annual Report* (Feb. 5, 2016), *available at* <https://www.hhs.gov/foia/reports/annual-reports/2015/index.html> (last visited November 2, 2017) (under Section VII.C. Processed Requested Granted Expedited Processing); U.S. Food and Drug Administration, *Freedom of Information Annual Report FY 2014* (May 21, 2015), *available at* <https://www.hhs.gov/foia/reports/annual-reports/2014/index.html> (last visited November 2, 2017) (under Section VII.C.3. Requests Granted Expedited Processing).
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