

AstraZeneca Data Requirements for Payments and Transfers of Value to Covered Recipients

The US Centers for Medicare and Medicaid Services (CMS) has been charged with implementation of the Physician Payment Sunshine Act, legislation that requires drug and device manufacturers to track and report all non-exempt Payments and Transfers of Value to US-licensed physicians and US teaching hospitals (“Covered Recipients”). A “Payment or Transfer of Value” is any payment or transfer of value as defined in the Sunshine Act (42 USC 1320(e)(10)), and implementing regulations (42 CFR 403.900 et seq.), and includes compensation, reimbursement for expenses, meals, travel, medical journal reprints, study drug, study supplies and medical writing and publications assistance. Detailed information about the Act is located on CMS’s OPEN PAYMENTS website: <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>.

Importantly, AstraZeneca’s transparency reporting obligations extend to direct and indirect payments and transfers to Covered Recipients by our research partners, suppliers and vendors. It is therefore critical that these partners collaborate with AstraZeneca in fulfilling these obligations.

There are also a number of US states that have transparency reporting laws that impose additional obligations. Where applicable, vendors working with AstraZeneca may be required to submit additional payment information to satisfy these state requirements.

Spend tracking systems. AstraZeneca has put in place multiple systems and processes that allow for accurate spend tracking and reporting. Where appropriate, a vendor may be provided with direct access to one of the systems, including:

- Viewpoint – used to track commercial (non-R&D) payments, travel, meals and expense reimbursement.
- ASPEN Invoicing (AI) – used to track R&D payments and transfers of value.
- ProTRAC – used to track Items of Value.
- ASPEN Data Entry (ADE) – use to track payments and transfers not captured in other systems.

OPEN PAYMENTS reporting formats. In accordance with OPEN PAYMENTS reporting specifications, the data required from our partners will vary depending upon whether a payment or transfer is made in connection with medical or scientific research:

- Payments or transfers of value made pursuant to a written agreement or protocol covering the conduct of a research study require information set forth in the **Research Report** specifications.
- All other payments or transfers of value require the information set forth in the **General Report** specifications.

The majority of the data requirements for these two reports are detailed in the tables on pages 3 and 4. For exact data requirements, or for additional details regarding AstraZeneca’s transparency reporting requirements, please visit the CMS OPEN PAYMENTS website or contact your AstraZeneca project manager.

Definitions. The Research Report and General Report data specifications use the following definitions:

- **Covered Recipient (CR)** – a US licensed physician or US teaching hospital.
- **PTOV** – a payment or transfer of anything of value to a Covered Recipient unless exempted.
- **Exempt PTOV** – a payment or transfer of value not required to be tracked or reported. Exempt PTOVs include: (i) patient education materials, (ii) samples/coupons/vouchers, (iii) discounts and rebates, (iv) buffet-style meals or snacks made available to participants at large-scale conferences or events, and (iv) items of value under \$10 made available to participants at large-scale conferences or events.
- **Items of Value (IOV)** – items that possess a value on the open market, such as textbooks, study drug and journal subscriptions.
- **Research Payments** – payments or transfers of value made pursuant to a written agreement or protocol covering the conduct of a research study or project. These payments will follow the CMS Research Report format.
- **General Payments** – payments or transfers of value that do not qualify as Research Payments. Payments related to research that are not covered by a written study agreement or protocol are General Payments. These payments follow the CMS General Report format.
- **Indirect Payments** – payments to a Covered Recipient through one or more third parties.
- **Related Entity Payments** – a payment to a third party on behalf of, or at the request of, a Covered Recipient. This would be the case when a physician directs a vendor to pay the physician's employer or practice group instead of the physician directly.
- **Entity Paid** – the name of the organization that received the Related Entity Payment on behalf of the Covered Recipient (e.g., employer name, group or individual practice name).
- **Site** – the location where the research activity is taking place, including teaching hospitals, non-teaching hospitals, laboratories, medical offices and other healthcare facilities.
- **Principal Investigator (PI)** – the lead scientist with primary responsibility for the design, execution or management of a research project at a research site.

GENERAL REPORT DATA REQUIREMENTS

COVERED RECIPIENT INFORMATION		
LAST NAME of US physician	or	NAME of US Teaching Hospital
FIRST NAME		ADDRESS line 1
MIDDLE INITIAL		ADDRESS line 2
SUFFIX		CITY, STATE, ZIP
CITY, STATE, ZIP		
IDENTIFIER		IDENTIFIER
<ul style="list-style-type: none"> • NPI NUMBER or 		<ul style="list-style-type: none"> • NPI NUMBER or
<ul style="list-style-type: none"> • SSN or 		<ul style="list-style-type: none"> • EIN
<ul style="list-style-type: none"> • STATE LICENSE number 		
AZID NUMBER (if available)		AZID NUMBER (if available)
ENTITY PAID INFORMATION (FOR RELATED ENTITY PAYMENTS)		
Is this a RELATED ENTITY PAYMENT? (Y/N)		
ENTITY PAID NAME		
ENTITY PAID ADDRESS line 1		
ENTITY PAID ADDRESS line 2		
CITY, STATE, ZIP		
ENTITY PAID IDENTIFIER		
<ul style="list-style-type: none"> • NPI NUMBER or 		
<ul style="list-style-type: none"> • EIN or 		
<ul style="list-style-type: none"> • AZID NUMBER 		
PTOV INFORMATION		
AMOUNT of the payment (cash)	or	VALUE of the transfer of value (in-kind)
DATE of the PTOV		
DRUG NAME connected with an AZ product		
DESCRIPTION of the PTOV		
NATURE of the PTOV		
<ul style="list-style-type: none"> • SPEAKER FEE or 		
<ul style="list-style-type: none"> • CONSULTANT FEE or 		
<ul style="list-style-type: none"> • EDUCATION or 		
<ul style="list-style-type: none"> • RESEARCH or 		
<ul style="list-style-type: none"> • MEAL or 		
<ul style="list-style-type: none"> • ADVISORY BOARD FEE or 		
<ul style="list-style-type: none"> • ROOM RENTAL FEE (teaching hospital only) or 		
<ul style="list-style-type: none"> • RECRUITING FEE or 		
<ul style="list-style-type: none"> • PUBLICATION FEE or 		
<ul style="list-style-type: none"> • MARKET RESEARCH FEE or 		
<ul style="list-style-type: none"> • GRANT or CONTRIBUTION or 		
<ul style="list-style-type: none"> • TRAVEL/LODGING or 		CITY, STATE and COUNTRY of travel destination
<ul style="list-style-type: none"> • GIFT 		
ITEM OF VALUE INFORMATION		
ITEM NAME		
ITEM DESCRIPTION		
FAIR MARKET VALUE (in US dollars)		
QUANTITY		

RESEARCH REPORT DATA REQUIREMENTS

STUDY SITE INFORMATION		
SITE NAME		
SITE ADDRESS line 1		
SITE ADDRESS line 2		
SITE CITY, STATE, ZIP		
SITE IDENTIFIER		
• NPI NUMBER or		
• EIN		
SITE AZID NUMBER (if available)		
PAYEE INFORMATION		
PAYEE NAME (if different than Study Site)		
PAYEE ADDRESS line 1		
PAYEE ADDRESS line 2		
CITY, STATE, ZIP		
PAYEE IDENTIFIER SSN/EIN, NPI or AZID NUMBER		
PRINCIPAL INVESTIGATOR INFORMATION		
LAST NAME of PI for Site		
FIRST NAME		
MIDDLE INITIAL		
SUFFIX		
ADDRESS line 1		
ADDRESS line 2		
CITY, STATE, ZIP		
IDENTIFIER		
• NPI NUMBER or		
• SSN or		
• STATE LICENSE number		
AZID NUMBER (if available)		
STUDY INFORMATION		
STUDY NAME		
AZ STUDY IDENTIFIER		
DRUG/COMPOUND NAME		
Is this a PRE-CLINICAL STUDY? (Y/N)		
PTOV INFORMATION		
AMOUNT of the payment (cash)	or	VALUE of the transfer of value (in-kind)
DATE of the PTOV		
DESCRIPTION of the PTOV		