

Transfer of Value reporting – Methodological Note

1. Introduction

Clovis Oncology is committed to comply with laws and regulations that promote transparency around relationships between Healthcare Professionals (HCPs), Healthcare Organizations (HCOs) associated with Transfers of Value (ToVs).

Clovis Oncology perceives collaborative working relationships between HCPs/HCOs and life sciences companies as a positive driver for advancement in patient care and the development of innovative medicines. Indeed, as the primary point of contact with patients, the medical profession has valuable and expert knowledge on management of diseases. Therefore, Clovis Oncology perceives healthy working relationships with HCPs and HCOs as in the best interest of patients and is committed to disclose its payments in full transparency in line with applicable laws and industry codes (based on Clovis’ association membership commitments).

This methodological note intends to define Clovis Oncology methodology regarding ToV reporting for countries with requirements deriving from an industry code.

Countries in Scope: with current market authorization as of June 2020, Clovis Oncology has reporting requirements in the following countries: Austria, Belgium, Denmark, France, Germany, Portugal and the UK. However, note that Belgium, Denmark, France and Portugal are legal requirements and therefore this methodological note does not apply to them. As a consequence, this note focuses on Austria, Germany and the UK requirements.

2. Clovis Oncology methodology and related business decisions

While local associations provide guidance regarding reporting of ToV, some elements need to be decided by the company. Accordingly, in this chapter, Clovis Oncology defines more precisely the elements that are disclosed and the decisions taken while creating reports.

A. Clovis Oncology activities per ToV category

Under the disclosure templates for ToV disclosure, different categories have to be reported. Clovis Oncology identified the following activities in each ToV category defined by the codes:

Category of spend	Details
Donations and grants to HCOs	<ul style="list-style-type: none"> • Donations and grants that support healthcare (including in-kind benefits)
Contributions to costs related to events to HCPs and HCOs	<p>Events include all scientific professional meetings, congresses, conferences, symposia and similar events. Costs include:</p> <ul style="list-style-type: none"> • Sponsorships agreements • Registration fees • Travel and accommodation such as: <ul style="list-style-type: none"> ○ Fees for airfare, train, boat or ferry (incl. booking fees) ○ Parking fees, tolls, car rental, taxi transfers ○ Drinks and meals

	<ul style="list-style-type: none"> • Rent of booths • Advertisement space
Fees for services and consultancy to HCPs and HCOs	<ul style="list-style-type: none"> • Fees for services and consultancy such as speaker fees, training fees, medical writing, data analysis, development of educational materials etc. • Expenses related to fees for service and consultancy such as: <ul style="list-style-type: none"> ○ Fees for airfare, train, boat or ferry (incl. booking fees) ○ Parking fees, tolls, car rental, taxi transfers ○ Drinks and meals
Research and Development	<ul style="list-style-type: none"> • Non-clinical (Good Laboratory Practice, GLP) • Clinical trials from Phase 1 to 4 • Investigator Sponsored Studies • Non-interventional studies

B. Reporting period

Clovis Oncology reports data based on the local requirements as follow:

Country	Date of disclosure	Data disclosed
Austria	June 30	Previous calendar year
Germany	June 30	Previous calendar year
UK	March 29	Previous calendar year

C. Direct and indirect spend

Direct transfers of value are defined as payments or in-kind elements made directly by Clovis Oncology to HCPs and HCOs. Indirect transfers of value are made through a third-party vendor on behalf of Clovis Oncology to HCPs and HCOs. In case of indirect payments, Clovis Oncology may not be able to identify the final recipient. If the final recipient knows that Clovis Oncology is the sponsor, Clovis Oncology requires its vendors to share the HCPs and HCOs transfers of value made and the applicable consent captured in order to report these transfers of value.

D. Consent

Clovis Oncology is committed to comply both with privacy and transparency requirements and accordingly collect consent for individual disclosure based on local requirements:

- if consent is given for all engagements, Clovis Oncology will disclose all elements in the individual section;
- if consent is not given for all engagements, Clovis Oncology will disclose all elements at an aggregated level, which is in line with EFPIA recommendations to avoid cherry picking;
- if consent is not captured by Clovis Oncology, Clovis Oncology will default all transfers of value to the aggregated section of the report.

Revoking individual consent: Clovis Oncology gives the options to HCPs and HCOs to revoke their consent prior to and after the disclosure of its transfers of value data. In if this occurs prior to the publication of the reports, Clovis Oncology will include this spend in the aggregated section of the reports.



If revocation of consent is made after the publication of the data, Clovis Oncology will remove personal data about transfers of value related to that HCP or HCO from the report disclosed, at least by the end of the month following the month of which the request has been received.

E. Events cancelled or HCPs not participating

Clovis Oncology will attribute only transfers of value that can be reasonably associated to an HCP. If a flight or accommodation is booked but the HCP is either not coming or if this is cancelled, no transfer of value will be attributed to that HCP.

F. In-kind donations

The transactional value of donations in kind is perceived by Clovis Oncology as the applicable transfer of value, which means that this is what will be disclosed (i.e. not the purchasing cost).

G. Cross border interactions

Transfers of value will be disclosed in the country of the principal HCP or HCO practice, professional address or place of incorporation.

H. Multi-year contract

In case of multiple year contracts or activities crossing calendar years, Clovis Oncology will disclose transfers of value based on their date of payment.

I. Rounding

Clovis Oncology rounds every transfers of values to the nearest digit in its transparency reports.

J. Currency

Clovis Oncology discloses transfers of value in the local currency of the country with disclosure requirements. In case of payments made in other currencies than the one required for disclosure requirements, Clovis Oncology will use the actual currency exchange rates based on the date of payment.

K. VAT

Expenses related to events and meetings will be disclosed including VAT. Fees and honoraria consultancy are excluding VAT and recoverable local taxes.

L. Reporting Platforms

Clovis Oncology reports its ToV on central platforms when available and on its website when no central platform exists. If Clovis Oncology does not have a local website, disclosure will be made on its website.

M. Out of scope Transfers of Values

Payments to Charity and Third Parties: occasionally, HCPs providing a service to Clovis Oncology may ask for their fee to be paid to a charity or a third party instead. Clovis Oncology typically does not allow this practice, the disclosure of transfers of values is accordingly made directly in the HCP's name. This is because the contract is actually made between Clovis Oncology and the HCP. It is up to the HCP to transfer the payment upon receipt to a charity of third party. This kind of transaction post-payment is outside of the control of Clovis Oncology.

3. Definitions (in line with Clovis Oncology Global Transparency SOP)

Healthcare Professionals (HCPs)	<p>Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.</p> <p>The definition of HCPs includes: (i) any official or employee of a government, agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer medicinal products and (ii) any employee of a pharmaceutical company whose primary occupation is that of a practicing HCP, but excludes all other employees of pharmaceutical companies and a wholesaler or distributor of medicinal products.</p> <p>It is important to note that the country-specific laws and regulations (including industry association codes) determine the relevant definition of an HCP</p>
Healthcare Organizations (HCOs)	<p>Any legal person/entity (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society or (ii) through which one or more HCPs provide services.</p> <p>It is important to note that the country-specific laws and regulations (including industry association codes) determine the relevant definition of an HCO.</p> <p>Independent of such definition or the EFPIA definition above, the term HCO used within this procedure shall encompass Patient Organizations to the extent spend capture, data stewardship and aggregation are concerned hereunder.</p>
Transfer of Values (ToV)	<p>Any direct and indirect benefit incurred on behalf of, payment made to, or provision of an item or service of value to an HCP or an HCO. This can include honoraria paid to an HCP in connection with services provided under a consulting agreement, reimbursement of expenses and/or a service or item paid for directly by Clovis as a benefit to an HCP (e.g., taxi fare or a meal). Payments to HCOs can include medical educational grants, donations, support for research and investigator-initiated trials.</p> <p>It is important to note that the country-specific laws and regulations (including industry association codes) determine the relevant definition of a Transfer of Value and to what extent and in what manner such Transfer of Value needs to be reported (e.g. non-financial support provided to POs).</p>
Consent to individual disclosure	<p>In some countries, due to privacy reasons, consent of HCPs and HCOs must be captured prior to individually disclose the ToV spend. In case, consent is not given by an HCP or HCO, the spend will still be disclosed be at an aggregated level.</p>
In-kind donations	<p>Transactional value of the materials given to the medical community by Clovis Oncology (these donations are in line with applicable laws and codes)</p>