ANNEXE 1: METHODOLOGY

Data collection

Data was collected via a reproductive health R&D module which was linked to the G-FINDER neglected disease survey. In consultation with our international Expert Advisory Group (EAG, see Annexe 2), organisations involved in reproductive health R&D were identified for participation. These organisations were asked to report every in-scope reproductive health R&D grant they had disbursed or received in 2013.

Thirty-one organisations reported reproductive health R&D data in the first year of the G-FINDER expansion into reproductive health (see Annexe 3 for a list of survey participants).

All respondents used the same definitions, categories and inclusion/exclusion criteria (see Annexe 4). We only accepted primary grant data. If accurate primary data was not available, we did not substitute secondary data or estimates.

Data was collected over a six-week period from May to June 2014, during which intensive follow-up and support were provided to key participants.

Data from participating multinational pharmaceutical companies and small pharmaceutical and biotechnology firms was aggregated in order to protect their confidentiality.

Survey scope

As discussed in the Introduction, commercial R&D investments into new reproductive health products for wealthy markets were excluded from this report since they are driven by, and targeted at, populations in HICs. People in LMICs may benefit from these investments, but the research would still be done even if DCs did not exist.

This report only includes R&D investments specifically targeting men and women in LMICs. This R&D work may be aimed at developing new or adapted products that are more affordable, heat stable, or deliverable via oral or vaginal routes rather than intravenously or intramuscularly; or at establishing or improving the safety and efficacy of products for patients who are also affected by diseases that disproportionally affect LMICs such as HIV/AIDS, malaria or tuberculosis.

Given the complexities in distinguishing between investments targeting HICs from investments targeting LMICs, we worked closely with our EAG to identify reproductive health issues specific to DC settings. This process resulted in the following list of reproductive health R&D areas: PPH, contraceptives, non-HIV STIs, MPTs, platform technologies for reproductive health and core funding of a reproductive health R&D organisation.

Some of these R&D areas were restricted to only include DC-specific investments (e.g. for contraceptive drugs, only products specifically designed for LMIC settings were included). Basic research was also excluded since this early-stage research cannot be allocated to a specific developed or developing country application.

Funding for the development of MPTs that include a microbicide – previously included in the neglected disease G-FINDER report as HIV/AIDS microbicides R&D – is now included in this report. Other R&D funding for HIV/AIDS is reported in the annual neglected disease G-FINDER report.

Handling of financial data

The collection principles used by the G-FINDER survey to handle key financial data were also used to handle the data included in this report. These principles included:

- Survey recipients were asked to enter grant-by-grant expenditures incurred during their financial year (as opposed to the 2013 calendar year) that had the largest overlap with 2013. PDPs and other intermediaries and product developers were also asked to enter grant-by-grant revenue during the same period
- Only expenditures were included, as opposed to commitments made but not yet disbursed or 'soft' figures such as in-kind contributions, costs of capital, or funding estimates
- All figures are reported in 2013 US dollars. Any data entered by survey participants in their local currency was converted to US dollars based on the 2013 average annual exchange rate as reported by the IMF.[39-42]

Survey tool and process

In order to be as consistent and comprehensive as possible across the range of reproductive health conditions surveyed, we followed two core principles:

1. Only primary data reported by the funders, PDPs and other intermediaries, and product developers themselves was included in the survey. If this data was not available, it was not supplemented with secondary data or estimates
2. All primary grant data was collected using the same online/offline reporting tool and inclusion/exclusion framework for all survey recipients

Survey tool

Survey participants were asked to enter every DC-specific reproductive health R&D investment they had disbursed or received in their financial year 2013 into a password-protected online database, including the grant amount, grant identification number, a brief description of the grant and the name of the funder or recipient of the grant. They were also asked to confirm their organisation details such as role in funding (e.g. funder, fund manager, product developer), financial year, currency used, type of organisation (e.g. private sector firm, academic institution, PDP, multilateral organisation), and country where they were located.

Each grant was entered using a three-step process where the survey recipient had to choose (1) a specific reproductive health condition; (2) a product type (e.g. drugs, diagnostics); and (3) a research type within the product (e.g. discovery and preclinical, clinical development); according to pre-determined categories (see Annexe 4). Where survey recipients could not provide data to this level of detail, they were asked to provide the finest level of granularity they could.

If survey recipients were not able to allocate the grant to a single condition in step 1, three options were available:

- ‘Platform technologies for reproductive health’
- ‘Core funding of a reproductive health R&D organisation’ (e.g. funding to an organisation working in multiple reproductive health areas, where the expenditure per area was not known to the funder)
- If survey recipients were not able to allocate the grant to a single product in step 2 or a single research type in step 3, they had the option to select ‘Unspecified reproductive health R&D’.

Data cleaning

Survey closure was followed by a period of intensive cleaning, cross-checking, and organising of the complex dataset collected.

All grants were verified through a four-step process:

1. Each grant was reviewed against our inclusion criteria. Over 355 grants were manually checked for correct allocation
2. Grants identified as borderline in terms of scope were reviewed in consultation with the EAG
3. Automated reconciliation reports were used to cross-check ‘disbursed’ funding reported by funders against ‘received’ funding reported by recipients
4. Uncovered discrepancies were resolved through direct contact with the funder and recipient to identify the correct figure. In the few cases where discrepancies still remained, the funder’s figures were used.

Limitations to interpretation

As with all surveys, there are limitations to the data presented. Potential limitations include:

Survey non-completion

Although strenuous efforts were made to identify all organisations active in reproductive health R&D, some reproductive health R&D funding might not have been captured because organisations were not identified and therefore were not invited to participate, or were invited to participate, but did not respond.

While data from major public funders is close to 100% complete, private sector investments might be under-reported due to the lack of company participation. Only five companies reported DC-specific reproductive health R&D data in 2013. Also, the lack of participation from DC firms means likely under-reporting in reproductive health areas where these firms are active.

Response rate

Differing levels of responsiveness between organisations and countries may also skew the findings. For instance, the Australian location of the G-FINDER group may have encouraged higher levels of responsiveness from Australian funders, while funders in non-English speaking settings may have been less enthusiastic in their levels of response. This is not known to have occurred.

Time lags in the funding process

Time lags exist between disbursement and receipt of funding, as well as between receipt of funds and the moment they are actually spent. Thus, grants by funders will not always be recorded as received by recipients in the same financial year and there may be a delay between R&D investments as reported by G-FINDER and actual expenditure on R&D programmes by product developers and researchers.

Inability to disaggregate investments

Funding allocated to some conditions and products may be underestimated due to:

- Organisations working across multiple reproductive health conditions: Core funding grants to organisations working on multiple conditions are not counted within the funding figures for specific conditions
- Investments for multiple conditions: When funders were unable to disaggregate grants for multiple reproductive health conditions within scope, these investments were included in the 'Unspecified reproductive health R&D' category. This methodology was followed to prevent double-counting investments
- Investments in shared areas: When funders were unable to disaggregate grants for developed markets from investments into DC-specific products, these investments were excluded. This might have led to under reporting.

Missing data

We can only report the data as it is given to us. Although strenuous efforts were made to check the classification, accuracy and completeness of grants, data might have been incorrectly entered or funders may have accidentally omitted some grants. We believe, however, that the checks and balances built into the process mean that such mistakes, if present, will have a minor overall impact.